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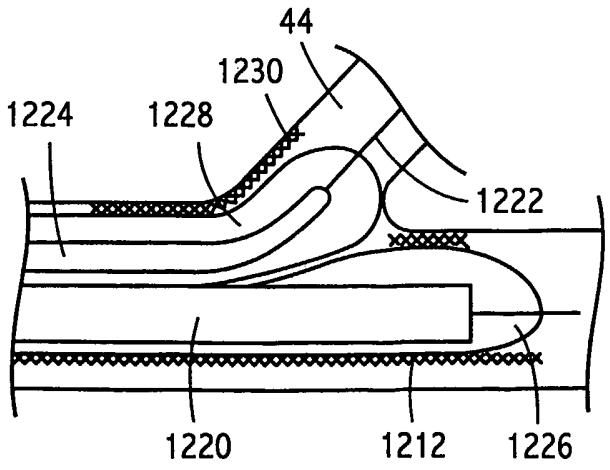
(54) Title: CATHETER BALLOON SYSTEMS AND METHODS



(57) Abstract: A system for treatment of a bifurcation of a body lumen, the bifurcation having a main vessel and a branch vessel, the system includes a catheter having a main catheter (1220 and a first balloon (1226) associated with the main catheter shaft, a side sheath (1224) and a second balloon (1220) associated with the side sheath, and a stent (1212) including a generally cylindrical body and a branch portion (1230). A method is also described which includes advancing a catheter system through the main vessel, positioning a branch portion of a stent present in the system proximate to a branch vessel, and inflating first and second balloons thereby expanding a main body and branch portion of the stent.

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CATHETER BALLOON SYSTEMS AND METHODS

[0001] The present application in a Continuation-in-Part of co-pending U.S. Patent Application Serial No. 10/834,066, filed April 29, 2004, which claims the benefit of priority of U.S. Provisional Application No. 60/488,006 filed July 18, 2003; U.S. Provisional Application No. 60/518,870 filed November 12, 2003; U.S. Provisional Application No. 60/547,778 filed February 27, 2004; and U.S. Provisional Application No. 60/548,868 filed March 2, 2004. The present application is also a Continuation-in-Part of co-pending U.S. Patent Application Serial No. 10/802,036, filed March 17, 2004, which is, in turn, a Continuation-in-Part of co-pending U.S. Patent Application Serial No. 10/705,247, filed November 12, 2003, and is a Continuation-in-Part of co-pending U.S. Application Serial No. 09/668,687, filed September 22, 2000, which is a Continuation-in-Part of U.S. Patent Application Serial No. 09/326,445, filed June 4, 1999, now U.S. Patent No. 6,325,826, and is a Continuation-in-Part of co-pending U.S. Patent Application Serial No. 10/440,401, filed May 19, 2003, which is a Continuation of U.S. Patent Application Serial No. 09/750,372, filed December 27, 2000, now U.S. Patent No. 6,599,316, and is a Continuation-in-Part of U.S. Patent Application Serial No. 09/963,114, filed September 24, 2001, now U.S. Patent No. 6,706,062, which is a Continuation of U.S. Patent Application Serial No. 09/326,445, filed June 4, 1999, now U.S. Patent No. 6,325,826, which is a Continuation-in-Part of International Application No. PCT/US99/00835, filed January 13, 1999. The present application is also a Continuation-in-Part of co-pending U.S. Patent Application Serial No. 10/644,550 filed August 21, 2003, which claims the benefit of priority to U.S. Provisional Application No. 60/404,756 filed August 21, 2002, U.S. Provisional Application No. 60/487,226 filed July 16, 2003, and U.S. Provisional Application No. 60/488,006 filed July 18, 2003. The present application claims the benefit of priority of U.S. Provisional Application No. 60/488,006, filed July 18, 2003. The complete disclosures of the above-referenced applications are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to the field of medical balloon catheters and, more particularly, to systems for delivering a stent at or near a bifurcation of a body lumen.

BACKGROUND OF THE INVENTION

[0003] Balloon catheters, with or without stents, are used to treat strictures, stenoses, or narrowings in various parts of the human body. Devices of numerous designs have been utilized for angioplasty, stents and grafts or combination stent/grafts. Varied catheter designs have been developed for the dilatation of stenoses and to deliver prostheses to treatment sites within the body lumen.

[0004] Illustrative procedures involving balloon catheters include percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA), which may be used to reduce arterial build-up such as caused by the accumulation of atherosclerotic plaque. These procedures involve passing a balloon catheter over a guidewire to a stenosis with the aid of a guide catheter. The guidewire extends from a remote incision to the site of the stenosis, and typically across the lesion. The balloon catheter is passed over the guidewire, and ultimately positioned across the lesion.

[0005] Once the balloon catheter is positioned appropriately across the lesion, (e.g., under fluoroscopic guidance), the balloon is inflated, which breaks the plaque of the stenosis and causes the arterial cross section to increase. Then the balloon is deflated and withdrawn over the guidewire into the guide catheter, and from the body of the patient.

[0006] In many cases, a stent or other prosthesis must be implanted to provide support for the artery. When such a device is to be implanted, a balloon catheter which carries a stent on its balloon is deployed at the site of the stenosis. The balloon and accompanying prosthesis are positioned at the location of the stenosis, and the balloon is inflated to circumferentially expand and thereby implant the prosthesis. Thereafter, the balloon is deflated and the catheter and the guidewire are withdrawn from the patient.

[0007] Administering PTCA and/or implanting a stent at a bifurcation in a body lumen poses further challenges for the effective treatment of stenoses in the lumen. For example, dilating a main vessel at a bifurcation may cause narrowing of the adjacent branch vessel. In response to such a challenge, attempts to simultaneously dilate both branches of the bifurcated vessel have been pursued. These attempts include deploying more than one balloon, more than one prosthesis, a bifurcated prosthesis, or some combination of the foregoing. However, simultaneously deploying multiple and/or bifurcated balloons with or without endoluminal prostheses, hereinafter individually and collectively referred to as a bifurcated assembly, requires accurate placement of the assembly. Deploying multiple stents requires positioning a main body within the main vessel adjacent the bifurcation, and then attempting to position another stent separately into the branch vessel of the body lumen. Alternatives to that include deploying a dedicated bifurcated stent including a tubular body or trunk and two tubular legs extending from the trunk. Examples of bifurcated stents are shown in U.S. Patent No. 5,723,004 to Dereume et al., U.S. Patent No. 4,994,071 to MacGregor, and U.S. Patent No. 5,755,734 to Richter et al.

[0008] Additional bifurcation stent delivery systems that provide improved reliable treatment at bifurcations are disclosed, for example, in U.S. Patent No. 6,325,826 to Vardi et al. and U.S. Patent No. 6,210,429 to Vardi et al. The contents of these aforementioned patents are incorporated herein by reference.

[0009] A need still exists for further improved devices and techniques for treating a bifurcated body lumen. For example, a need further exists for additional stent delivery systems that can be used with stents having a branch access side hole and/or an extendible branch portion, of the type disclosed in U.S. Patent No. 6,210,429.

SUMMARY OF THE INVENTION

[0010] The present invention is directed to devices and techniques for treating a bifurcated body lumen including systems for delivering an endoluminal prosthesis at or near a bifurcation of a body lumen. Systems, devices and techniques are disclosed comprising balloon catheters configured to successfully and reliably deploy stents at a

bifurcation in a body lumen. Additionally, the balloon catheters can be employed as balloon angioplasty catheters to treat occlusions in blood vessels such as for instance in percutaneous transluminal coronary angioplasty (PTCA) procedures.

[0011] According to one aspect, the present invention provides a system for treatment of a bifurcated body lumen, the bifurcated body lumen comprising a main vessel and a branch vessel, the system comprising: a catheter comprising a main catheter shaft and a first balloon associated with the main catheter shaft; a side sheath and a second balloon associated with the side sheath; and a stent comprising a generally cylindrical body defining an outer perimeter having a proximal end and a distal end and a branch portion; wherein the stent is positioned relative to the side sheath such that the first balloon is adapted to expand the main body portion of the stent, and the second balloon is adapted to extend the branch portion toward the branch vessel, and wherein the second balloon is located radially inward of the outer perimeter when the second balloon is not inflated.

[0012] According to another aspect, the present invention provides a system for treatment of a bifurcated body lumen, the bifurcated body lumen comprising a main vessel and a branch vessel, the system comprising: a catheter comprising a main catheter shaft and a first balloon associated with the main catheter shaft; a side sheath and a second balloon associated with the side sheath; and a stent comprising a generally cylindrical body having a proximal end and a distal end, a branch portion, and a branch access opening; wherein the start is positioned relative to the side sheath such that the first balloon is adapted to expand the main body portion of the stent, and the second balloon is adapted to extend the branch portion toward the branch vessel, and the second balloon is longitudinally located between the proximal end and the distal end of the stent; and wherein at least a portion of the side sheath extends through the branch access opening.

[0013] According to yet another aspect, the present invention provides a method for treating a bifurcated body lumen, the bifurcated body lumen comprising a main vessel and a branch vessel, the method comprising: (i) advancing a catheter system through the main vessel, the catheter system comprising: a main catheter shaft and a first balloon associated with the main catheter shaft; a side sheath and a second balloon associated

with the side sheath; and a stent comprising a generally cylindrical body having a proximal end, a distal end, a branch portion, and a branch access opening; wherein at least a portion of the side sheath extends through the branch access opening; and wherein the second balloon is longitudinally located between the proximal end and the distal end of the stent; (ii) positioning the branch portion of the stent proximate to the branch vessel; (iii) inflating the first balloon thereby causing expansion of the generally cylindrical body of the stent; and (iv) inflating the second balloon thereby causing the branch portion of the stent to be pushed outward with respect to the generally cylindrical body of the stent.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented to provide what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention.

[0015] FIG. 1 is a side view of an illustrative embodiment of a stent delivery system constructed in accordance with the present invention.

[0016] FIG. 2 is an enlarged side view taken of the distal portion of the system of FIG. 1.

[0017] FIG. 3 is a view of the stent delivery system of FIG. 1 in a blood vessel shown approaching a bifurcation in the vessel without a stent mounted thereon in accordance with a method of the present invention.

[0018] FIG. 4 is a view of the system of FIG. 3, including a stent mounted thereon.

[0019] FIG. 5 is a view of the stent delivery system of FIG. 1 in a blood vessel located at a bifurcation in the vessel without a stent mounted thereon in accordance with a method of the present invention.

[0020] FIG. 6 is a cross-sectional side view of the stent delivery system of FIG. 1 with a stent mounted thereon and shown in the expanded condition.

[0021] FIG. 7 is a perspective view of a balloon configured according to one embodiment of the present invention.

[0022] FIG. 8 is a perspective view of a balloon constructed according to an alternative embodiment of the present invention.

[0023] FIG. 9 is a perspective view of a balloon configured according to a further embodiment of the present invention.

[0024] FIG. 10 is a perspective view of a balloon configured according to yet another alternative embodiment of the present invention.

[0025] FIG. 11 is a perspective view of a balloon configured according to another embodiment of the present invention.

[0026] FIG. 12 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention.

[0027] FIG. 13 is a perspective view of the expandable branch portion of the stent of FIG. 12 in the expanded configuration.

[0028] FIG. 14 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention.

[0029] FIG. 15 is an enlarged view of a portion of the stent of FIG. 14.

[0030] FIG. 16 is a view of the expandable branch portion of the stent of FIG. 14 in the expanded configuration.

[0031] FIG. 17 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention.

[0032] FIG. 18 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention.

[0033] FIG. 19 is a view of an expandable branch portion of the stent of FIG. 18 in the expanded condition.

[0034] FIG.20 is a schematic view of a stent in the expanded state implemented at a blood vessel bifurcation.

[0035] FIG. 21 is a schematic view of the stent of an alternative construction in the expanded state implemented at a blood vessel bifurcation.

[0036] FIG. 22 is a perspective view of an alternative stent delivery system for inserting a stent in accordance with another system and method of the present invention.

[0037] FIGS. 23 – 26 are illustrations of the steps for a method of inserting a stent according to one embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0038] The present invention relates to balloon catheters such as balloon angioplasty catheters to treat occlusions in blood vessels. The balloon catheters can be used alone or with a stent, prosthesis or graft. Such a stent delivery system can be used for placement of a stent in a body lumen, particularly at vessel bifurcations. A preferred stent to be delivered is generally configured to at least partially cover a portion of a branch vessel as well as a main vessel. In general, a wide variety of stents and deployment methods may be used with the stent delivery system embodiments of the present invention and the present invention should be understood to not be limited to any particular stent design or configuration. Examples of the types of stents that may be used with the delivery systems of the present invention are disclosed, for example, in U.S. Patent No. 6,210,429 to Vardi et al., U.S. Patent No. 6,325,826 to Vardi et al., co-pending U.S. Patent Application No. 10/802,036 entitled "Stent With Protruding Branch Portion For Bifurcated Vessels," and co-pending U.S. Patent Application No. 10/644,550, entitled "Stent With a Protruding Branch Portion For Bifurcated Vessels," the entire contents of which are incorporated herein by reference. In general, the aforementioned stents include a branch portion located at some point along the length of the stent that is configured to be extendible into a branch vessel in a vessel bifurcation. Once the stent is in position in

the main vessel and the branch portion is aligned with the side branch vessel the stent can be expanded and the delivery system is particularly adapted to expand the stent branch portion into the side branch vessel. The stent, including the branch portion, may be expanded with a single expansion or multiple expansions as disclosed, for example, in co-pending U.S. Patent Application Serial No. 10/834,066, the entire content of which is incorporated by reference.

[0039] An illustrative view of one embodiment of a stent delivery system **10** constructed in accordance with the present invention is shown in FIG. 1. Stent delivery system **10** generally comprises an elongate main catheter shaft **12** extending from a proximal end **14** to a distal end **16**. As best seen in FIG. 2, distal end **16** has a bifurcated tip structure with two branch portions, a main vessel branch portion **18** and a side branch sheath **20** that branch off of main catheter shaft **12**. A bifurcated balloon **26** is attached to main vessel branch portion **18** adjacent the distal end **16** and comprises first and second branch portions **27, 30**. First branch portion **27** of balloon **26** comprises an elongate inflatable portion **28**. Second branch portion **30** of balloon **26** comprises a second or auxiliary balloon or inflatable portion **32**. Second branch portion **30** includes an inflation lumen that branches off from first branch portion **27** proximally from the balloon **26** and extends substantially adjacent elongate inflatable portion **28**. The distal end of second branch portion **30** is attached to first branch portion **27** at a location distally from the balloon **26**. In one preferred embodiment, the distal end of branch portion **30** is fixedly attached distally of balloon **26** in order to prevent at least the second inflatable portion **32** from moving around the first branch portion **27**, although in alternate embodiments it may be removably attached.

[0040] In a first embodiment, first inflatable portion **28** is generally cylindrical and extends coaxially along main vessel branch portion **18**. Second inflatable portion **32** may have a shape and size adapted to extend into the branch vessel as shown and described herein. For example, portion **32** may have a generally offset configuration and may be positioned adjacent or in abutting relation with respect to elongate inflatable portion **28**.

[0041] The first and second inflatable portions or balloons can have varied shapes, sizes and positioning in accordance with the principles of the invention. For example, in alternative design variations, accurate sizing and positioning of the inflatable portions relative to the vessel may be achieved.

[0042] According to the present invention, the inflatable portions, or balloons, can be constructed of any suitable material. For example, the balloons may be constructed of an appropriate polymeric material. Particular examples include the polyamide family, or the polyamide blend family, polyethylene (PE), polyethylene terephthalate (PET), polyurethanes, polyamides, and polyamide blends such as PBAX. The compliance of the first inflatable portion **28** and the second inflatable portion **32** can be the same or different. In one preferred embodiment, second inflatable portion **32** is longitudinally positioned at a generally central location relative to the first inflatable portion **28**. In alternate embodiments, second inflatable portion **32** may be positioned at any position adjacent first inflatable portion **28**.

[0043] In a preferred embodiment, balloon branch portions **27** and **30** have a common inflation lumen **34**. Inflation lumen **34** can be conventional, and extend from a portion of the stent delivery system which always remains outside of the patient (not pictured). Inflation lumen **34** extends distally into each of first and second branch portions **27** and **30** and thus, inflation lumen **34** is in fluid communication with the interiors of first inflatable portion **28** and second inflatable portion **32**. Thus inflation lumen **34** is used to supply pressurized inflation fluid to first inflatable portion **28** and second inflatable portion **32** when it is desired to inflate balloon **26**. Inflation lumen **34** is also used to drain inflation fluid from first inflatable portion **28** and second inflatable portion **32** when it is desired to deflate the balloon. First and second inflatable portions are initially deflated when directing the stent delivery device to the bifurcation lesion in a patient. In this embodiment, the inflation lumen **34** inflates inflatable portions **28, 32** substantially simultaneously. In an alternative embodiment, branch balloon portions **27** and **30** have separate inflation lumens. In this alternative embodiment inflatable portions **28** and **32** can be inflated simultaneously or sequentially. When sequential inflation is desired,

preferably, the first inflatable portion **28** is inflated first, followed by the inflation of the second portion **32**.

[0044] First main guidewire lumen **22** extends through main vessel branch portion **18** and first inflatable portion **28**. Although first guidewire lumen **22** extends through first inflatable portion **28** in the embodiment depicted in FIGS. 1-2, it is distinct from inflation lumen **34** and is not in fluid communication with the interior of balloon **26** as shown. Preferably, the first guidewire lumen **22** extends distally of first inflatable portion **28** and has an open distal end. Alternatively, guidewire lumen **22** can extend through branch portion **30**.

[0045] In the embodiment depicted in FIGS. 1-2, an optional side sheath **20** is illustrated which does not include an inflatable balloon. Although in alternative embodiments side sheath **20** could include an inflatable portion, as described in further detail herein. Side sheath **20** is exterior to and distinct from inflation lumen **34** and thus is also not in fluid communication with the interior of balloon **26** as shown. As shown in the embodiment of FIGS. 1-2, side sheath **20** preferably extends distally of balloon **26**, and may include a proximal open end **37** at any point along the length of the stent delivery system and a distal open end **39**. Side sheath **20** can be of the type as described in U.S. Patent No. 6,325,826 to Vardi, *et al.*, for example, and in operation the side sheath **20** can extend through a branch access hole of the stent (see, e.g., FIG. 4).

[0046] With reference to FIGS. 3-6, an exemplary manner of practicing the invention will now be discussed. Referring to FIGS. 3 and 5, the delivery system is shown in relation to an exemplary body lumen adjacent a blood vessel bifurcation **40** usually comprised of plaque and the delivery system **10** is shown without a stent mounted thereon (FIGS. 3 and 5). Figs. 4 and 6 show the stent delivery system **10** with a stent **50** mounted thereon.

[0047] Bifurcation **40** includes a main vessel **42** and a branch vessel **44**. Illustrative obstructions **46** located within bifurcation **40** may span or at least partially obstruct main vessel **42** and a proximal portion branch vessel **44**. Generally, stent delivery system **10** may be threaded over a first main guidewire placed in the main vessel to guide the

delivery system to the treatment site. More specifically, the proximal end of first guidewire **36** is threaded into the distal open end of the main guidewire lumen **22** and the delivery system is tracked to a position at or near bifurcation **40**, as depicted in FIG. 3. Second guidewire **38** (FIG. 5) is then threaded into stent delivery system **10** from the proximal end of the delivery system. More specifically, second guidewire **38** is threaded into the open proximal end **37** of side sheath **20**, and may extend therefrom through the open distal end **39** of side sheath **20**, as depicted in FIG. 5. Alternatively, second guidewire **38** can be resting dormant on the inside of the side sheath, and when the system is proximal the bifurcation **40**, it can be advanced out of side sheath **20** into side branch vessel **44**. The systems in accordance with the principles of the invention may be used in over-the-wire or rapid exchange systems, which may include rapid exchange on either or both of the side sheath or main catheter. Rapid exchange is described in one exemplary embodiment in US2003/0181923 to Vardi et al., published September 25, 2003, the entire contents of which are incorporated herein by reference.

[0048] In one embodiment, the stent delivery system **10** is positioned near bifurcation **40**, and with the distal end **16** (FIG. 1) positioned near side branch vessel **44** (FIGS. 3-6), second guidewire **38** is advanced into side branch vessel **44** from side sheath **20**. Then, the first and second inflatable portions of balloon **26** are positioned adjacent the opening of side branch vessel **44** such that auxiliary inflatable side portion **32** of bifurcated balloon **26** is aligned with side branch vessel. In one exemplary embodiment, alignment may be achieved using markers, as described in U.S. Patent No. 6,692,483 to Vardi, *et al.*, the entire contents of which is incorporated herein by reference. Second guidewire **38** remains in side branch sheath **20**, and the distal end **16** of system **10** remains in main vessel **42**. First guidewire **36** remains within first guidewire lumen **22**, and may be further advanced and positioned in main branch vessel **42**.

[0049] Once the system is properly positioned, pressurized fluid is supplied to first and second inflatable portions **28** and **32**, respectively, of balloon **26** to dilate the body lumen and expand a stent mounted thereon (FIG. 6). Preferably, the inflatable portion **28** expands the main body of the stent and inflatable portion **32** expands the side (opening) and expandable branch structure of the stent, as discussed in more detail with reference to

FIG. 6. After inflatable portions **28** and **32** have been inflated as described above, balloon **26** is deflated by draining the inflation fluid via inflation lumen **34**. This allows the inflatable portions **28** and **32** to collapse in preparation for withdrawal of the assembly from vessel **42**.

[0050] Referring now to FIGS. 4 and 6, one preferred embodiment is shown with stent delivery system **10** and an exemplary stent **50** mounted on the exterior of distal end **16** of the stent delivery system. Stent **50** includes an extendible branch portion **52** configured to extend into a branch vessel as will be discussed in further detail herein. The second inflatable portion **32** may be configured and positioned to deploy the outwardly expanding stent elements or branch portion **52** and may be positioned adjacent to the branch portion **52**, or into a side branch access opening in the stent. As illustrated in FIG. 4, the second inflatable portion is preferably located radially within the outer periphery of the stent **50** prior to inflation. As shown in FIG. 6, when first and second inflatable portions **28** and **32** are expanded, they simultaneously or sequentially, depending upon the configuration of the inflation lumen, cause the stent **50** to expand in the main vessel **42** and the branch portion **52** of stent **50** to be pushed or extended into the branch vessel **44**. Upon inflation of the balloon **26**, the second inflatable portion **32** expands and extends the branch portion **52** toward the branch vessel to open and support the entrance or ostium of the side branch artery. This would occur simultaneously when the balloons share a common inflation lumen but could be sequentially inflated if separate inflation lumens are used. Although a bifurcated balloon is depicted, as shown, more than two inflatable portions or more than two balloons may be utilized with the present invention.

[0051] As illustrated, for example, in FIGS. 5 and 6, the first and second branch portions **27** and **30** have a longitudinal axis **A**. The longitudinal axies are substantially parallel with each other. The term "substantially parallel" is intended to encompass deviations from a purely parallel relationship which may be caused by flexure of the branch portions **27** and **30**, or other components, experienced during insertion, travel, and deployment within a body lumen.

[0052] Various alternative balloon configurations will now be described which are designed to facilitate expansion of a branch structure portion of a stent.

[0053] FIG. 7 is an enlarged perspective view of the second balloon or auxiliary inflatable portion **32** of bifurcated balloon **26**, which is referred to in the previous embodiments depicted in FIGS. 1-6. According to this embodiment, the central portion **33** of the auxiliary inflatable side portion **32** extends in a generally equidistant manner from the longitudinal axis **A**, and at an angle of up to about 90° relative to longitudinal axis **A**, but other angles are contemplated. As illustrated in FIG. 7, the auxiliary inflatable side portion **32** can have a generically spherical central portion **33** which is connected to a proximal shaft **41**, as well a distal shaft **43**. The components of the auxiliary inflatable side portion **32** may be sized appropriately, as will be readily apparent to those skilled in the art. The central spherical portion **33** can be provided with a suitable inflated diameter D. The diameter D can vary according to various factors known to those skilled in the art. According to a non-limiting, exemplary embodiment, the diameter D can be on the order of a few millimeters. For example, the diameter D is on the order of about 1.5–6.0mm and, preferably, on the order of about 3.34–3.36mm.

[0054] FIG. 8 illustrates an alternative second balloon or auxiliary inflatable side portion construction **132**. According to this embodiment, the central portion **133** of the auxiliary inflatable side portion **132** extends in a generally equidistant manner from the longitudinal axis **A**, and at an angle of up to about 90° relative to longitudinal axis **A**, but other angles are contemplated. As illustrated in FIG.8, the balloon **132** comprises a generally elliptical central portion **133**, as well as a proximal shaft portion **141**, and distal shaft **143** connected thereto. As with the previous embodiment, the various components of the balloon **132** may be sized as appropriate within appropriate dimensional ranges, as determined by those skilled in the art. The elliptical central section **133** of the balloon **132** is provided with major and minor diameters, D_1 and D_2, respectively, as illustrated in FIG.7. According to non-limiting exemplary embodiments, the elliptical central section may be shaped such that the ratio D_2/D_1 is on the order of about 0.8. According to further exemplary non-limiting embodiments, the major diameter D_1 is preferably on the order of

about 3.65–3.85mm and can range from 1.5-6mm, while the minor diameter D_2 is smaller than D_1 and is preferably on the order of about 2.9–3.1mm.

[0055] FIG.9 illustrates yet a further embodiment of a second balloon or auxiliary inflatable side portion **232** of bifurcated balloon **26** constructed according to the principles of the present invention. According to this embodiment, the central portion **232** is offset relative to the longitudinal axis **A** and preferably extends toward and/or into the branch vessel **44**. The central portion **232** may extend at an angle of up to about 90° relative to longitudinal axis **A**, but other angles are contemplated. As illustrated in FIG. 9, the auxiliary inflatable side portion **232** of balloon **26** comprises an offset central bulbous or generally spherical portion **233**, with a proximal shaft portion **241** and distal shaft portion **243** connected thereto via a proximal transition section 241_T and distal transition 243_T, respectively. As with the previous embodiments, the various components of the auxiliary inflatable side portion **232** of balloon **26** can be sized as appropriate, and as readily determined by those skilled in the art. According to exemplary, non-limiting embodiments, the auxiliary inflatable side portion **232** of balloon **26** can be configured such that the central offset portion **233** is provided with a radius of curvature **R** which is on the order of about .50–3.0mm.

[0056] FIG. 10 illustrates yet another alternative embodiment for a second balloon or auxiliary inflatable side portion **332** of bifurcated balloon member **26**. According to this embodiment, the central portion **332** is offset relative to the longitudinal axis **A** and preferably extends toward and/or into the branch vessel **44** (not shown). The central portion **332** may extend at an angle of up to about 90° relative to longitudinal axis **A**, but other angles are contemplated. As shown in FIG. 10, the auxiliary inflatable side portion **332** is configured such that it comprises a generally offset elliptical and cylindrical central section **333**, with proximal shaft portions **341** and distal shaft portions **343** connected thereto via proximal transition section 341_T and distal transition portion 343_T, respectively. The offset central section **333** is preferably configured such that it comprised a first diameter D_1 and second diameter D_2 wherein D_1 and D_2 have different values ($D1 \neq D2$). The dimensions of the various constituent components of the auxiliary inflatable side portion **332** can be determined by those skilled in the art. According to

exemplary non-limiting embodiments, the auxiliary inflatable side portion **332** can be configured such that it is provided with first and second diameters such that the ratio D_2/D_1 is on the order of about 0.25–4.0mm. According to further, non-limiting examples, the auxiliary inflatable side portion **332** can be configured such that it is provided with a first diameter D_1 which has dimensions on the order of about 1.5–6.0mm and, preferably about 2.7–2.9mm, and a second diameter D_2 which has dimensions on the order of about 1.5–6.0mm, and preferably about 2.1–2.3mm.

[0057] FIG. 11 illustrates yet another alternative embodiment of a second balloon or auxiliary inflatable side portion **432** of bifurcated balloon **26**. According to this embodiment, the central portion **432** is offset relative to the longitudinal axis **A** and preferably extends toward and/or into the branch vessel **44** (not shown). The central portion **432** may extend at an angle of up to about 90° relative to longitudinal axis **A**, but other angles are contemplated. The auxiliary inflatable side portion **432** is configured such that it comprises an offset generally cylindrical central section **433** having a proximal shaft portion **441** and a distal shaft portion **443** connected thereto via proximal transition shaft portion 441_T and distal transition portion 443_T, respectively. The various constituent components of the balloon **432** can be configured with relative dimensions which can be ascertained by those skilled in the art. According to exemplary, non-limiting examples, the balloon **432** can be configured such that it is provided with an offset generally cylindrical central section **433** having a diameter **D** which is on the order of about 1.5–6.0mm.

[0058] Various alternative stent constructions will now be described by reference to FIGS. 12-21.

[0059] Referring now to FIGS. 12 and 13, an alternate embodiment of stent **569** is shown and includes an alternate branch portion **530**. In this particular embodiment, branch portion **530** comprises support struts **570** and an expandable ring **572**. Branch portion **530** defines at least one side opening **574**. In one embodiment, the dimensions of the cell defining side opening **574** are such that the side opening **574** (prior to expansion of the stent) is larger than other openings in stent body **514**. The presence of side opening **574**

is generally configured to accommodate a side sheath therethrough and allow a physician to access a branch vessel during or after a procedure. In a particular embodiment, as shown in FIG. 12, side opening **574** is surrounded by expandable ring **572** of continuous material. In alternative embodiments, expandable ring **572** comprises unattached portions, or one portion that only partially covers side opening **574**. A series of support struts **570** connect expandable ring **572** with struts **524** and connectors **526**. Support struts **570** preferably comprise patterns in a folded or wrap-around configuration that at least partially straighten out during expansion, allowing expandable ring **572** to protrude into the branch vessel.

[0060] In this embodiment, when stent **569** is expanded, as shown in FIG. 13, branch portion **530** is extended into the branch vessel, causing expandable ring **574** to at least partially cover the inner surface of the branch vessel. Thus, in a preferred embodiment, the stent coverage in a portion the branch vessel includes the full circumference of the inner branch vessel wall. In alternative embodiments, partial coverage or several sections of coverage are present.

[0061] Referring to FIGS. 14-16, another embodiment of a stent **679** is shown having a main stent body **614** and another embodiment of a branch portion **630**. FIGS. 14 and 15 show stent **679** in the unexpanded condition where branch portion **630** has not been deployed. FIG. 28 shows the stent **679** in the expanded configuration where the branch portion **630** has been expanded. As shown, main stent body **614** includes a main stent pattern having generally repeatable ring **628** and connector **626** pattern. Branch portion **630** and the surrounding midsection **680** interrupt the repeatable ring **628** and connector **626** pattern of stent **679**. In this embodiment, branch portion **630** is configured to be both radially expandable and longitudinally extendable into the branch vessel and relative to its longitudinal axis **681** so that, in a preferred embodiment, the branch portion **630** contacts the entire periphery or circumference of the inner wall of the branch vessel in the expanded configuration. In this regard, branch portion **630** preferably provides 360° coverage of the wall of the branch vessel. That is, branch portion **630** can be extended outward with respect to longitudinal axis **681** of stent **679**, and can also be expanded

radially about axis **683** so as to contact the vessel (thereby allowing it to be adjustable with respect to vessel size).

[0062] Referring to FIG. 15, an enlarged view of section **680** of stent **679** is shown. In a preferred embodiment, a structural support member **684** may be provided as a transition between the main stent body **614** and branch portion **630**. In one aspect of a preferred embodiment, structural support member **684** may be elliptical to accommodate branch vessels extending at an angle to the main vessel. In alternate embodiment, other shapes of support members **684** can be used to accommodate the vasculature. The structural support member **684** may include a continuous ring. In this embodiment, structural support member **684** is a full, non-expandable ring and it does not expand radially beyond a particular circumference.

[0063] As shown in FIGS. 14 and 15, two concentric rings, inner ring **686** and outer ring **688**, are positioned within structural support member **684** and surround a generally circular branch opening **634** to provide access to the side branch vessel when stent **679** is in the unexpanded condition. Rings **686** and **688** are interconnected by a plurality of inner connectors **690**. Outer ring **688** is connected to structural support member **684** by a plurality of outer connectors **692**. Rings **686** and **688** are generally curvilinear members. For example, rings **686**, **688** can be defined by undulation petals, prongs, or peaks **694**. In a preferred embodiment, each ring **686**, **688** have the same number of undulation peaks **694**, but the inner ring may be more closely or tightly arranged, as shown. In another preferred embodiment, each ring **686**, **688** has eight pedals or undulation peaks **694**, although in alternate embodiments each ring can have any number of undulation peaks, and the number of peaks need not be equal for each ring. The undulation peaks **694** generally include a pair of strut portions **696** interconnected by curved portions **698**, and the strut portions themselves are connected to adjacent strut portions by another curved portion. In a preferred embodiment, eight outer connectors **692** extend between structural support member **684** and outer ring **688**, and each outer connector **692** is attached at one end to approximately the middle of a strut portion **696** of outer ring **688** and the structural support member **684** at the other end. As shown, outer connectors **692** may also have an undulated shape, although in alternate embodiments outer connectors **692** may have

differing shapes. In another aspect of the preferred embodiment, outer connectors **692** may be evenly or symmetrically spaced about the structural support member **684**. The inner ring **686** is attached to the outer ring **688** by a plurality of inner connectors **690** and, in a preferred embodiment; eight inner connectors **690** connect the rings. Inner connectors **690** extend from curved portion **698** of outer ring **688** to curved portion of inner ring **686**. As shown in FIG. 15, in a preferred embodiment, inner connectors **690** have simple curved shape. Other qualities, configurations, sizes and arrangements of connectors, rings and spacing can be used depending upon the desired results. Varying the connectors can provide for different amounts of flexibility and coverage. The type of configuration of rings and connectors shown addresses the need for radial and longitudinal expansion of branch portion **630**, as well as branch vessel coverage. Other configurations and arrangements for the branch portion can be used in accordance with the invention.

[0064] Referring again to FIGS. 14 and 15, the stent pattern surrounding branch portion **630** may be modified with a different pattern to accommodate branch portion **630**, as can all of the aforementioned embodiments. In particular, the rings **628** in the midsection **680** may be configured and dimensioned to be denser to provide sufficient coverage and flexibility to composite for the area occupied by branch portion **630**.

[0065] Referring now to FIG. 16, stent **679** is shown in the expanded configuration, with branch portion **630** deployed. Upon expansion of branch portion **630**, the inner and outer rings **686, 688** shift about the longitudinal branch axis **683** and expand laterally away from the main stent body **614** and into the branch vessel to form a branch coverage portion. Upon expansion, the outer connectors **692** can move outwardly and the inner connectors **690** can straighten to a position substantially parallel to longitudinal branch axis **681**. In a preferred embodiment, the expanded rings **686, 688** have substantially the same expanded diameter, although in alternate embodiments rings **686, 688** could also have different diameters to accommodate a tapered vessel, if, for example a tapered balloon is used. The branch portion **630** can be extended at different angles to the longitudinal axis **681** of the stent depending upon the geometry of the branch vessel being

treated. In this embodiment, the branch portion **630** may preferably extend into the branch vessel about 1.5 – 3 mm.

[0066] Referring now to FIG. 17, another embodiment in the form of a stent **789** is shown having a main stent body **714** and another embodiment of a branch portion **730**. Stent **789** is substantially similar to stent **679**, except **789** has a discontinuous support member **704** surrounding a two concentric ring **786, 788** structure. Support member **704** has a generally elliptical shape and includes a plurality of discontinuities **706** along the perimeter. The configuration of the discontinuous support member facilitates additional flexibility of the branch portion during expansion and generally provides for accommodating a greater range of branch vessel geometries. In one aspect of a preferred embodiment, structural support member **784** may be elliptical to accommodate branch vessels extending at an angle to the main vessel.

[0067] Referring to FIGS. 18 and 19, another embodiment of a stent **899** is shown in the unexpanded and expanded states, respectively. Stent **899** comprises a main stent body **814** and another embodiment of a branch portion **830**. Stent **899** is substantially similar to stent **879**, except stent **899** has a branch portion **830** including a support member **808** surrounding three concentric rings **810, 812, 814** instead if two. As can be seen in FIG. 19, when stent **899** is expanded the three concentric ring structure of this embodiment facilitates additional branch wall support because a generally more dense pattern is created in branch portion **830** with the addition of another concentric ring.

[0068] In all of the above embodiments, the branch portion protrudes into the branch vessel when the stent is fully expanded. The branch portion upon expansion can extend into the branch vessel in different lengths depending upon the application. The amount of extension may vary in a range between about 0.1 –10.0 mm. In one preferred embodiment, the length of extension is 1-3 mm. In another preferred embodiment, the length of extension is approximately 2 mm. In alternative embodiments, the amount of extension into the branch vessel may be variable for different circumferential segments of the branch portion. As shown in each of the embodiments, the branch portion is approximately 2.5 mm in width and about 2.5 – 3.0 mm in length. However, the branch

portion can be dimensioned to accommodate varying size branch vessels. The branch portion can be formed of any tubular shape to accommodate the branch vessel, including, oval or circular, for example.

[0069] In all of the above embodiments, it should be understood that it is within the scope of the present invention to provide the stent with a configuration such that the proximal end of the stent is expandable to a greater or lesser degree than the distal end of the stent. For example, the stent, when expanded, may be constructed such that its outer diameter at the proximal end thereof is greater than the outer diameter at the distal end of the stent.

[0070] Referring to FIGS. 20 and 21, schematic views are shown of stents **912, 1029** in the expanded state as implemented at a blood vessel bifurcation. As shown in FIG. 20, stent **912** has a generally curved or radial profile along the distal perimeter **945** of branch portion **930** as it extends into branch vessel **44**. The generally curved or radial profile is due to the particular geometry of branch portion **930** of stent **912.** Referring to FIG. 21, stent **1029** has a generally tapered, straight or linear profile along the distal perimeter **1047** of the branch portion **1030** of the stent as it extends into branch vessel **44**. The generally straight or linear profile in FIG. 21 is a result of the particular geometry of branch portion **1030** of stent **1029**. In a preferred embodiment, the linear profile is at a right angle with respect to the axis of branch vessel **44**. In alternative embodiments, however, the linear profile may be at any angle with respect to the axis of branch vessel **44**. One advantageous feature of the linear profile along the distal perimeter of branch portion **1030** shown in FIG. 21 is that if a second stent **51** were to be used in branch vessel **44**, the linear profile facilitates better alignment with the second stent and permits coverage of a larger surface area of the branch vessel wall. For example, if a second stent **51** were to be used in combination with stent **912** of FIG. 20, gaps may exist between the two stents at the interface between the radial distal perimeter **945** and an abutting straight or linear edge of a second stent, whereas a close abutting interface may be achieved with stent **1029** of FIG. 21.

[0071] The balloon delivery systems and deployment methods of the previously described embodiments may be used with any of the aforementioned stent configurations. According to a further embodiment, the balloon configured to extend or expand the branch portion of the stent is located on the side sheath of the delivery system, such as the system **1138** depicted in FIG. 22. In this case, the system is a two-balloon system. As illustrated in FIG. 22, the second balloon is located such that the side sheath **1141** extends distally beyond the second balloon **1140**. The second balloon **1140** can be positioned within a stent in a manner similar to that previously described herein and is preferably located radially within the stent prior to inflation. The side sheath **1141** may have an inflation lumen and a lumen for receiving a guidewire **1142** for locating the branch vessel **44**. The second balloon **1140** may have a lumen for receiving a guidewire for locating the branch vessel. The second balloon may be located at any position along the length of the main balloon. For example, it can be located between proximal and distal ends of the stent, more particularly it can be located on the middle 1/3 of the stent. When employed on the side sheath, the second or auxiliary balloon **1140** can have the same shape or geometry as any of the previously described embodiments contained herein, such as those depicted in connection with FIGS. 6-11. In this regard, the proximal and distal shaft portions **41, 43, 141, 143, 241, 243, 341, 343, 441** and **443** of the balloon constructions illustrated in FIGS. 7-11 can be shaft portions of the side sheath **1141**. Moreover, any of the previously described stent configurations may also be used in combination with the system **1138**.

[0072] Referring now to FIGS. 23-26, illustrations of the steps of one alternative example of a method for employing a stent according to the invention are shown. By way of example, the method is depicted utilizing stent **1212**. Methods for positioning such a catheter system within a vessel and positioning such a system at or near a bifurcation are described more fully in co-pending U.S. Patent Application No. 10/320,719 filed on December 17, 2002, which is incorporated herein by reference in its entirety. As shown in FIG. 23, a catheter system **1220** is positioned proximal to a bifurcation, using any known method. A branch guidewire **1222** is then advanced through an opening in the stent and into the branch vessel **44**, as shown in FIG. 24. In a preferred embodiment, the opening may be a designated side branch opening, such as an opening formed by the

absence of some connectors, as described above. Branch portion **1230** is adjacent the opening. As shown in FIG. 25, if the side sheath **1224** is attached to the main catheter **1220**, the main catheter **1220** is advanced along with the side sheath **1224**. Alternatively, if the side sheath **1224** is separate from to the main catheter **120**, the second catheter or side sheath **1224** is then advanced independently through the opening in the stent and into the branch vessel. Branch portion **1230** is positioned over a portion of the lumen of the branch vessel **44** as the side sheath **1224** is inserted into branch vessel **44**. Referring to FIG. 26, a first balloon **1226** located on main catheter **1220** is then expanded, causing expansion of the stent body, and a second balloon **1228** located on the side sheath **1224** is also expanded, causing branch portion **1230** to be pushed outward with respect to the stent body, thus providing stent coverage of at least a portion of the branch vessel **44**. The balloons are then deflated and the catheter system and guidewires are then removed.

[0073] One particular application for the use of a stent with a branch portion **30** such as the one described above is for localizing drug delivery. As discussed herein, restenosis, including in-stent restenosis, is a common problem associated with medical procedures involving the vasculature. Pharmaceutical agents have been found to be helpful in treating and/ or preventing restenosis, and these are best delivered locally to the site of potential or actual restenosis, rather than systemically.

[0074] While the invention has been described in conjunction with specific embodiments and examples thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art upon reading the present disclosure. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. Furthermore, features of each embodiment can be used in whole or in part in other embodiments.

WE CLAIM:

1. A system for treatment of a bifurcated body lumen, the bifurcated body lumen comprising a main vessel and a branch vessel, the system comprising:

a catheter comprising a main catheter shaft and a first balloon associated with the main catheter shaft;

a side sheath and a second balloon associated with the side sheath; and

a stent comprising a generally cylindrical body having a proximal end and a distal end, a branch portion, and a branch access opening;

wherein the stent is positioned relative to the side sheath such that the first balloon is adapted to expand the main body portion of the stent, and the second balloon is adapted to extend the branch portion toward the branch vessel, and the second balloon is longitudinally located between the proximal end and the distal end of the stent; and

wherein at least a portion of the side sheath extends through the branch access opening.

2. The system of claim 1, wherein the main catheter shaft and the side sheath comprise a proximal end and a distal end, wherein the main catheter shaft and the side sheath are connected at the proximal end, and are separate at the distal end.

3. The system of claim 1, wherein the main catheter shaft and the side sheath are separate members.

4. The system of claim 1, wherein the side sheath extends distally beyond the second balloon.

5. The system of claim 1, further comprising a first inflation lumen associated with the first balloon and a second inflation lumen associated with the second balloon.

6. The system of claim 5, wherein the first and second inflation lumens are not in fluid communication with each other.

7. The system of claim 1, wherein the main catheter shaft comprises a guidewire lumen for passage of a guidewire to locate the catheter within the main vessel.

8. The system of claim 7, wherein the side sheath comprises a guidewire lumen for passage of a guidewire to locate the side sheath within the branch vessel.

9. The system of claim 1, wherein the inflatable portion of the second branch portion is generally spherical.

10. The system of claim 1, wherein the inflatable portion of the second branch portion is generally elliptical and comprises a major and minor axis

11. The system of claim 1, wherein the inflatable portion of the second branch portion is generally in the form of an offset bulbous shape.

12. The system of claim 1, wherein the inflatable portion of the second branch portion is generally in the form of an offset elliptical cylinder.

13. The system of claim 1, wherein the inflatable portion of the second branch portion is generally in the form of an offset cylinder.

14. The system of claim 1, the stent further comprising a branch access opening, and the branch portion comprises an outwardly expandable portion disposed around any portion of the branch access opening, wherein expanding the second balloon deploys the outwardly expandable portion of the stent toward the branch vessel.

15. The system of claim 1, wherein the generally cylindrical body of the stent comprises a geometrical configuration defining a first pattern comprising a pattern of struts and connectors, and the branch portion comprises a geometrical configuration defining a second pattern.

16. The system of claim 15, wherein the second pattern comprises a pattern of struts and connectors, and comprises a portion having at least one missing connector in the pattern.

17. The system of claim 16, wherein the portion has a plurality of missing connectors.

18. The system of claim 15, wherein the second pattern comprises a pattern of struts and connectors, and wherein the struts of the second pattern are more densely packed than the struts in the first pattern.

19. The system of claim 15, wherein the struts in the first pattern have a first length, and the struts in the second pattern have a second length, and wherein the first length is different than the second length.

20. The system of claim 15, wherein the struts in the first pattern have a first density, and the struts in the second pattern have a second density, and wherein the first density is different than the second density.

21. The system of claim 1, wherein the second balloon is longitudinally located in the middle one-third of the stent.

22. The system of claim 1, wherein the generally cylindrical body of the stent defines an outer perimeter, wherein the second balloon is located radially inward of the outer perimeter when the second balloon is not inflated.

23. The system of claim 1, wherein the proximal end of the stent is constructed such that it is expandable to a greater outer diameter than the distal end of the stent.

24. A system for treatment of a bifurcated body lumen, the bifurcated body lumen comprising a main vessel and a branch vessel, the system comprising:

a catheter comprising a main catheter shaft and a first balloon associated with the main catheter shaft;

a side sheath and a second balloon associated with the side sheath; and

a stent comprising a generally cylindrical body defining an outer perimeter having a proximal end and a distal end and a branch portion;

wherein the stent is positioned relative to the side sheath such that the first balloon is adapted to expand the main body portion of the stent, and the second balloon is adapted to extend the branch portion toward the branch vessel, and wherein the second balloon is located radially inward of the outer perimeter when the second balloon is not inflated.

25. The system of claim 24, wherein the branch portion of the stent comprises a branch access opening.

26. The system of claim 25, wherein at least a portion of the side sheath extends through the branch access opening.

27. The system of claim 24, wherein the first balloon and the second balloon are located between the proximal end and the distal end of the stent.

28. The system of claim 24, wherein the second balloon is longitudinally located in the middle one-third of the stent.

29. The system of claim 24, wherein the proximal end of the stent is constructed such that it is expandable to a greater outer diameter than the distal end of the stent.

30. The system of claim 24, wherein the proximal end of the stent is constructed such that it is expandable to a greater outer diameter than the distal end of the stent.

31. A method for treating a bifurcated body lumen, the bifurcated body lumen comprising a main vessel and a branch vessel, the method comprising:

(i) advancing a catheter system through the main vessel, the catheter system comprising:

a main catheter shaft and a first balloon associated with the main catheter shaft;

a side sheath and a second balloon associated with the side sheath; and

a stent comprising a generally cylindrical body having a proximal end, a distal end, a branch portion, and a branch access opening;

wherein at least a portion of the side sheath extends through the branch access opening; and wherein the second balloon is longitudinally located between the proximal end and the distal end of the stent;

(ii) positioning the branch portion of the stent proximate to the branch vessel;

(iii) inflating the first balloon thereby causing expansion of the generally cylindrical body of the stent; and

(iv) inflating the second balloon thereby causing the branch portion of the stent to be pushed outward with respect to the generally cylindrical body of the stent.

32. The method of claim 31, wherein the main catheter shaft and the side sheath comprise a proximal end and a distal end, wherein the main catheter shaft and the side sheath are connected at the proximal end, and are separate at the distal end.

33. The method of claim 31, wherein the main catheter shaft and the side sheath are separate members.

34. The method of claim 31, wherein steps (iii) and (iv) are performed simultaneously.

35. The method of claim 32, wherein steps (iii) and (iv) are performed sequentially.

36. The method of claim 31, wherein the first balloon and the second balloon are located between the proximal end and the distal end of the stent.

37. The method of claim 32, wherein at least one of steps (i) and (ii) comprise advancing the catheter system over at least one guidewire.

38. The method of claim 31, further comprising advancing at least a portion of the side sheath into the branch vessel.

39. The method of claim 31, wherein the expansion of the second balloon in step (iv) causes the branch portion of the stent to cover at least a portion of the branch vessel.

40. The method of claim 31, further comprising:

(v) deflating the first and second balloons; and

(vi) removing all components of the catheter system from the main and branch vessels, except for the stent.

41. The method of claim 31, wherein the second balloon is longitudinally located in the middle one-third of the stent.

42. The method of claim 31, wherein the generally cylindrical body of the stent defines an outer perimeter, wherein the second balloon is located radially inward of the outer perimeter when the second balloon is not inflated.

43. The method of claim 31, wherein step (iii) comprises expanding the proximal end of the stent to a greater degree than the distal end of the stent.

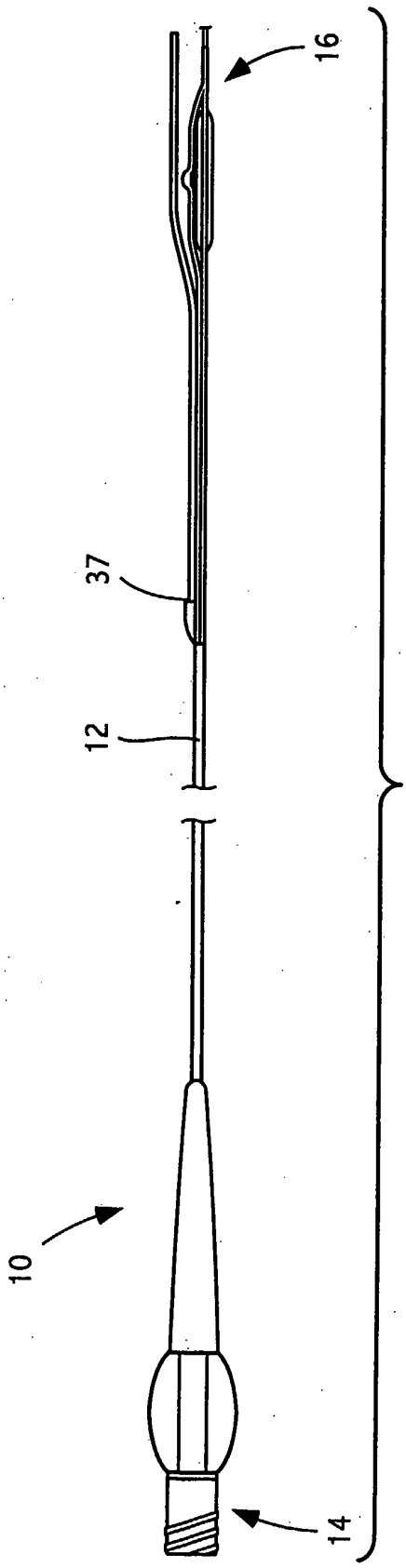


FIG. 1

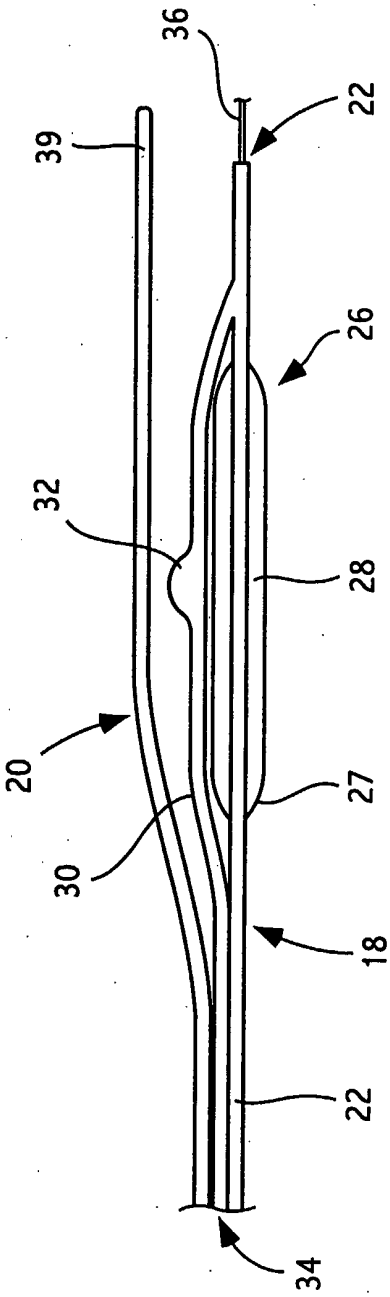


FIG. 2

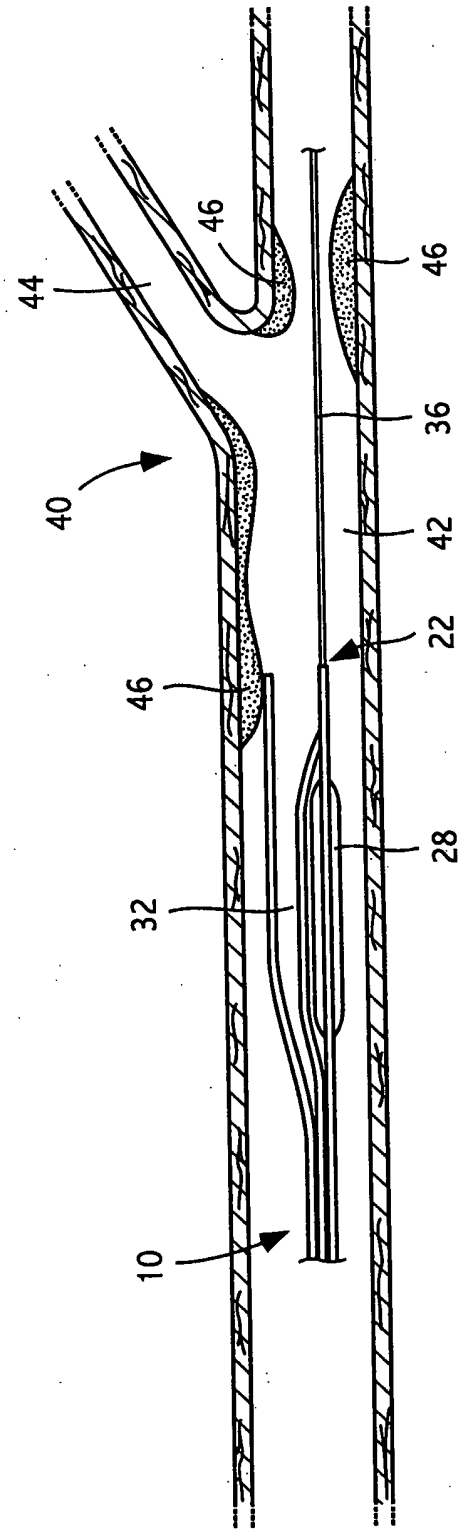


FIG. 3

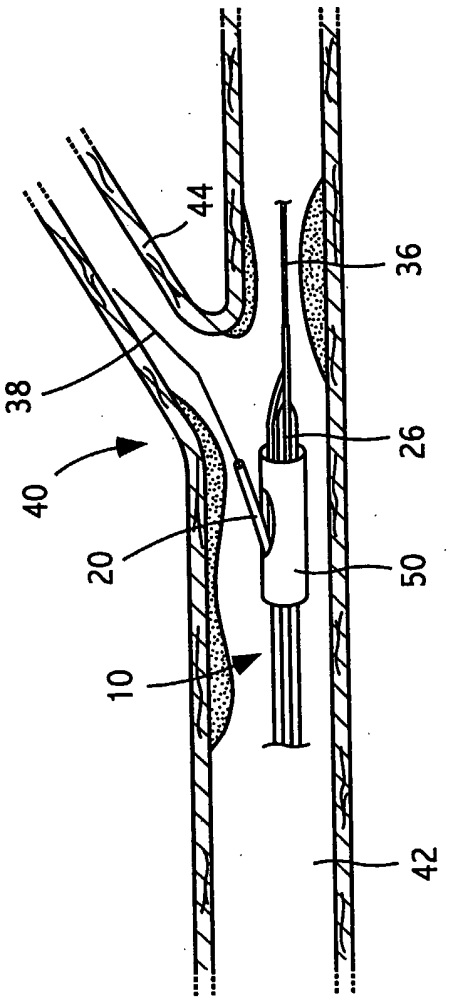


FIG. 4

FIG. 5

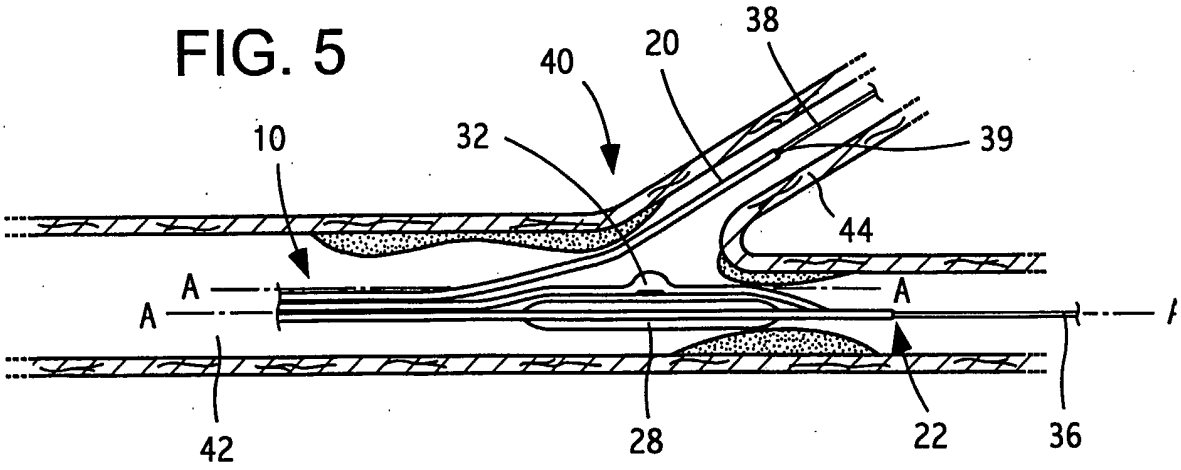


FIG. 6

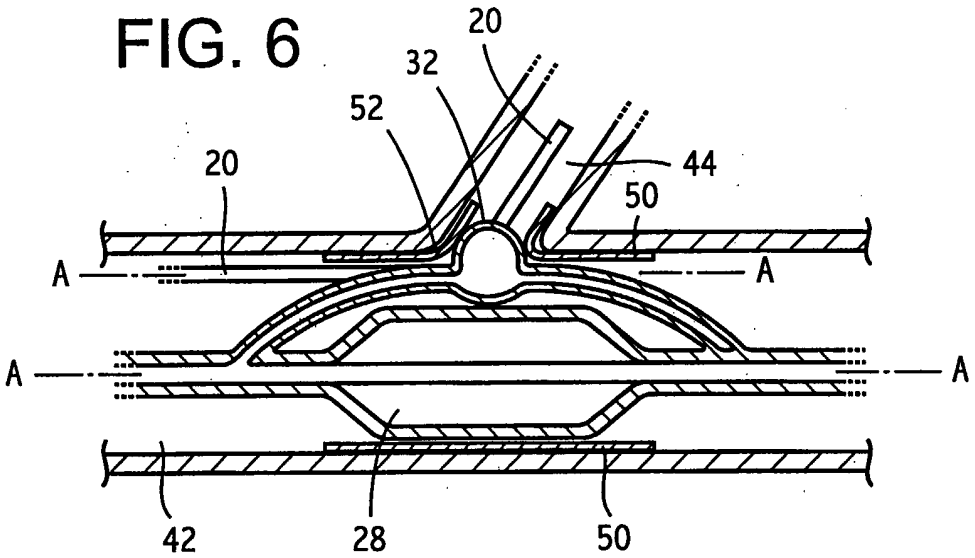
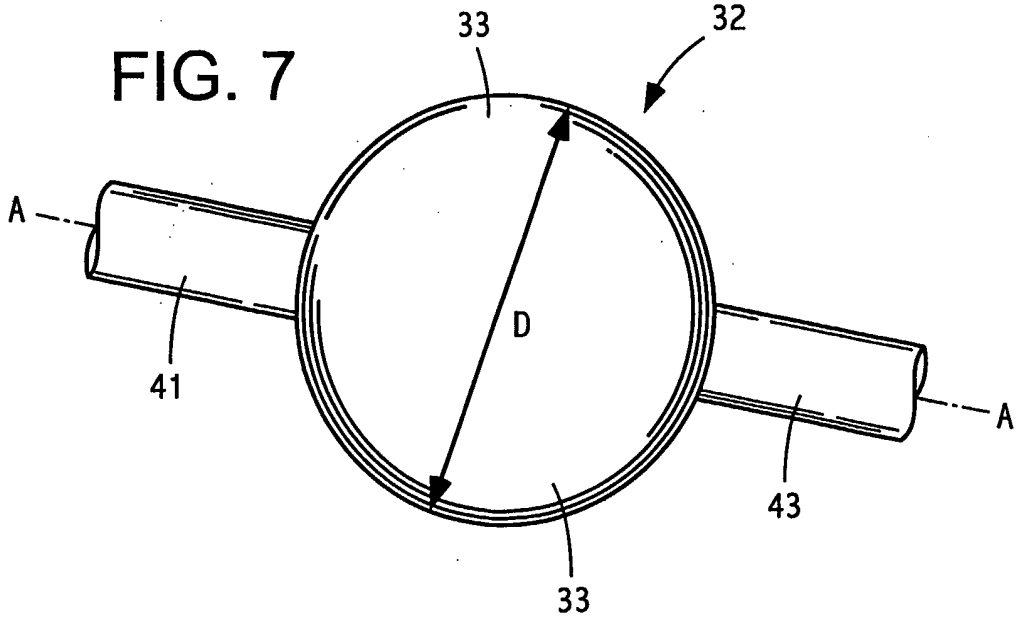


FIG. 7



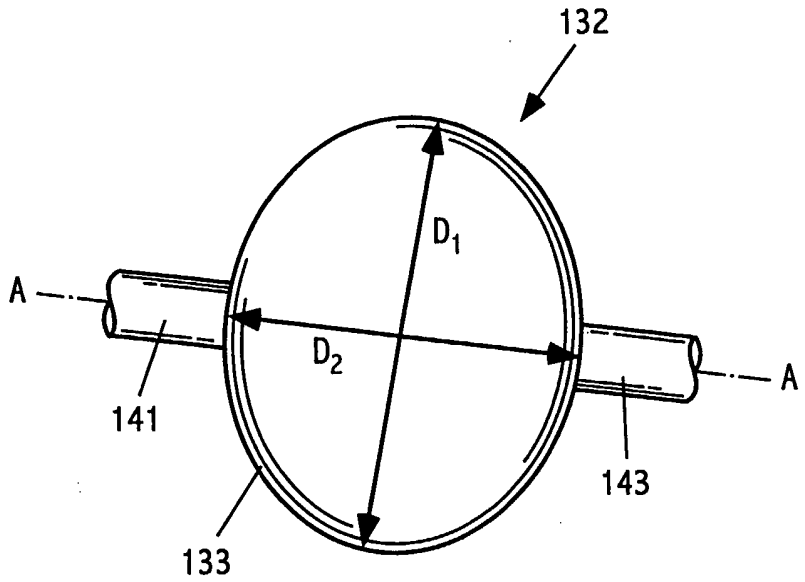


FIG. 8

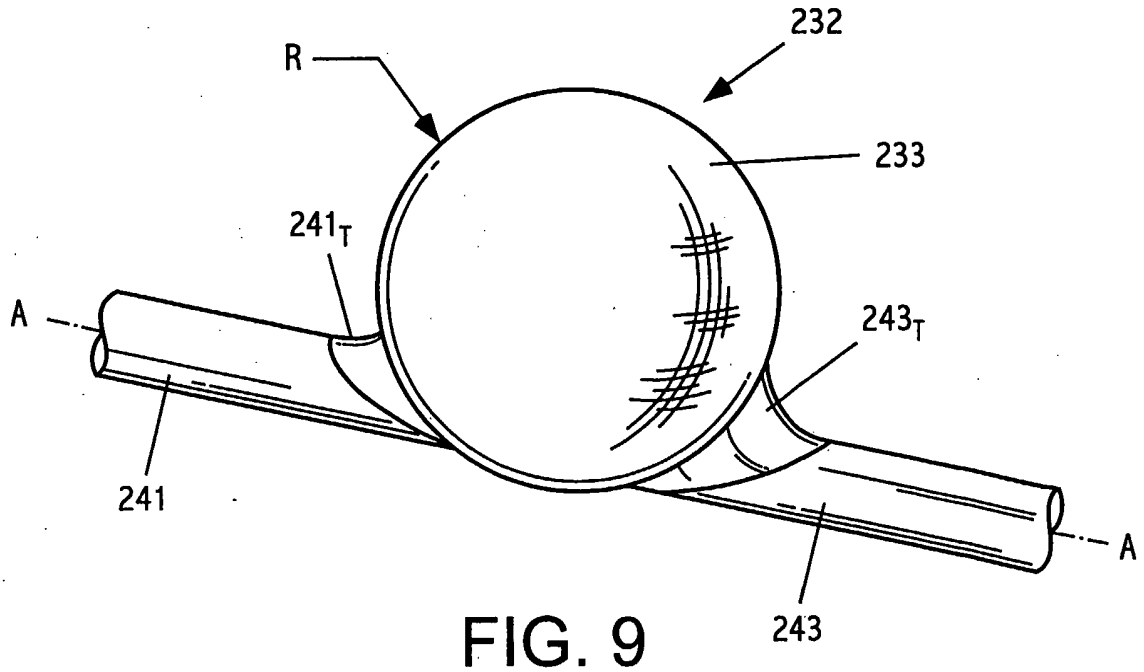


FIG. 9

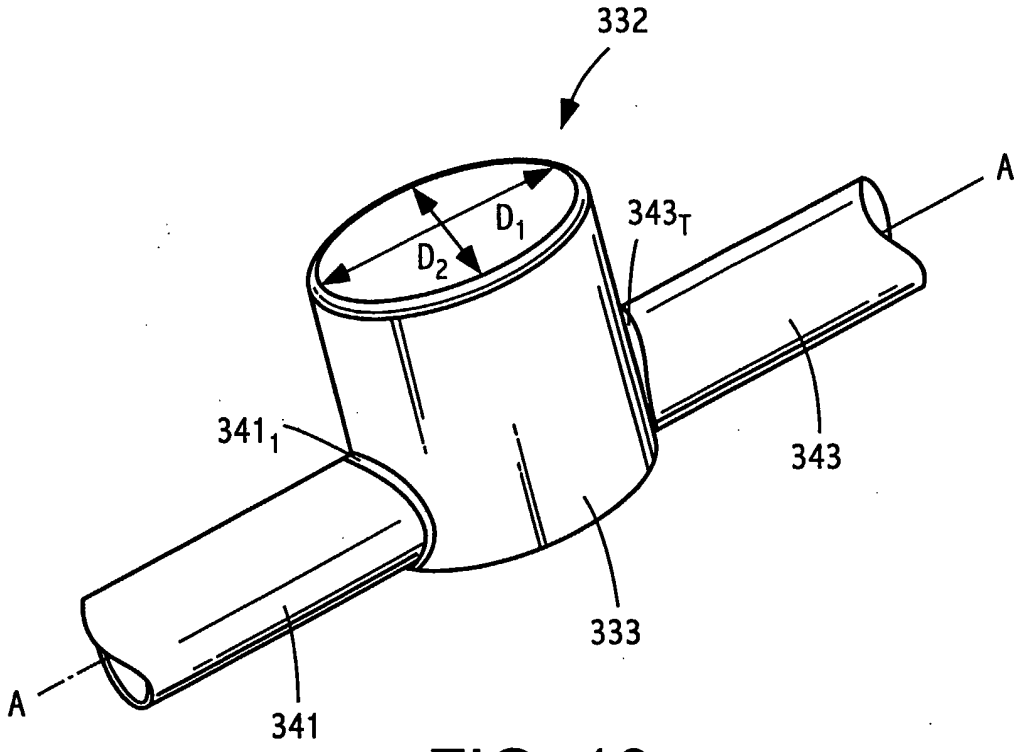


FIG. 10

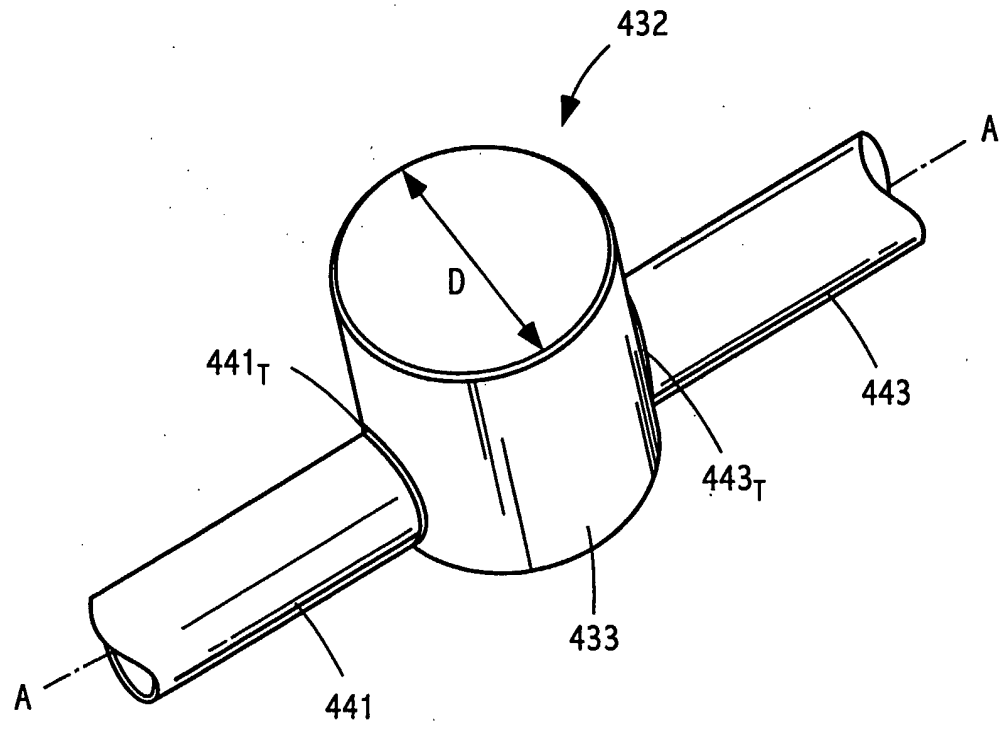


FIG. 11

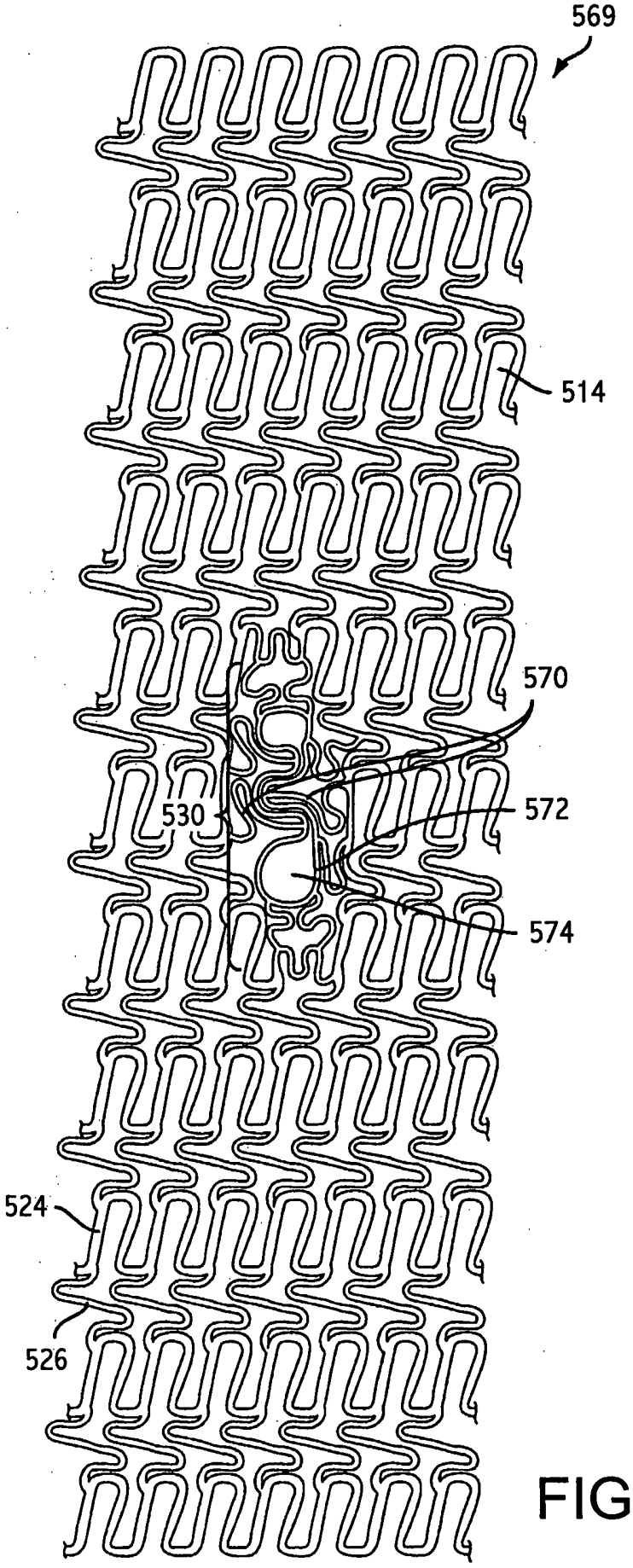


FIG. 12

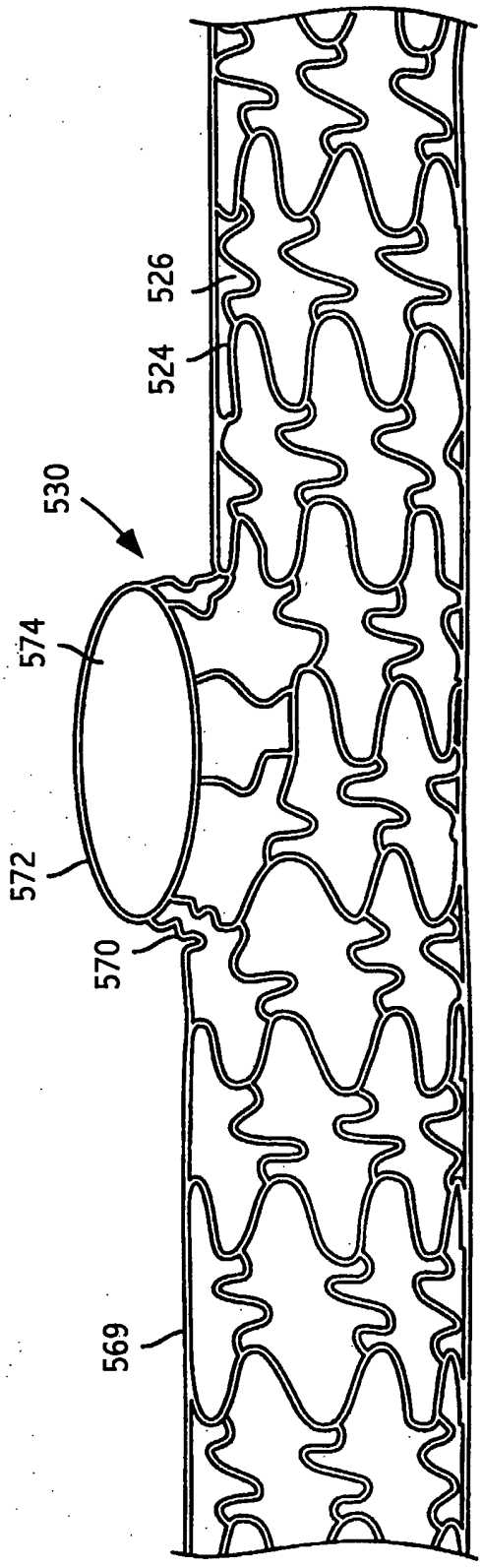


FIG. 13

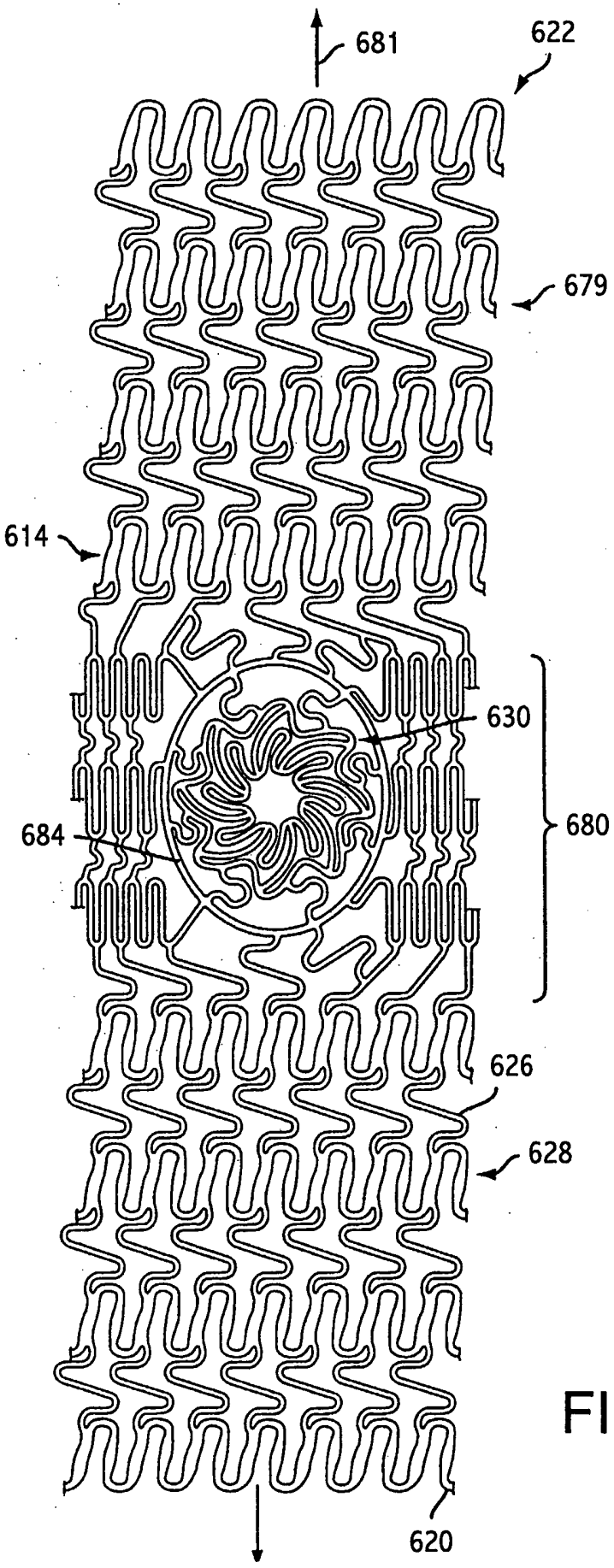


FIG. 14

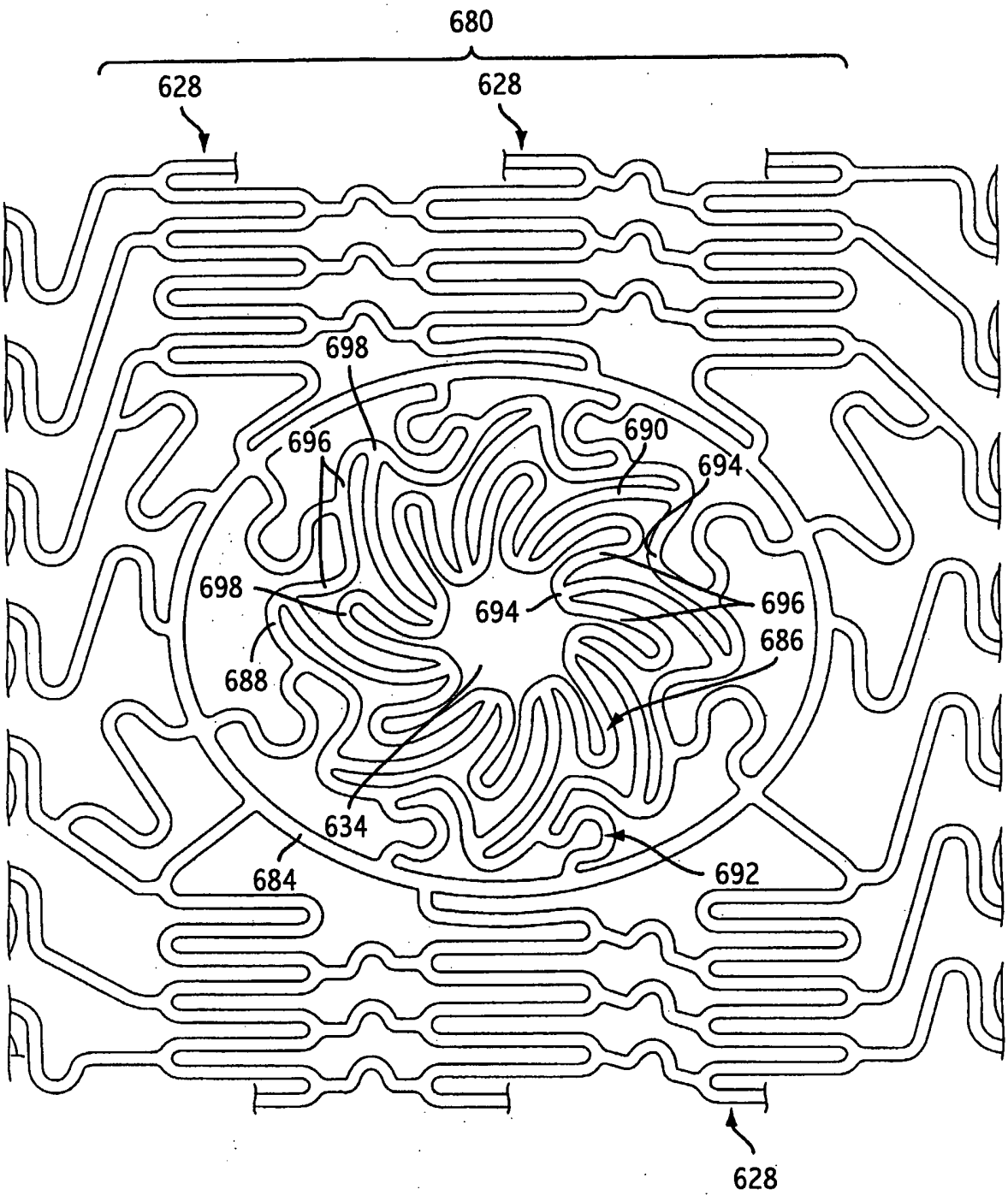


FIG. 15

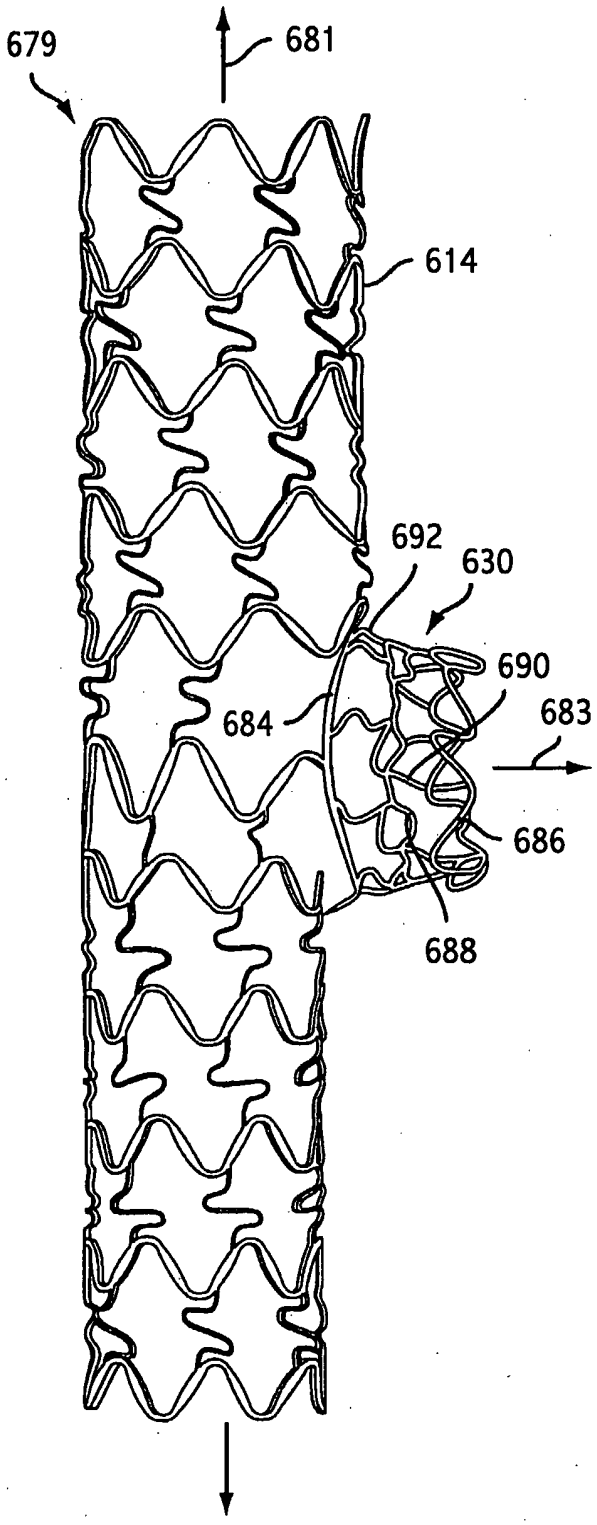


FIG. 16

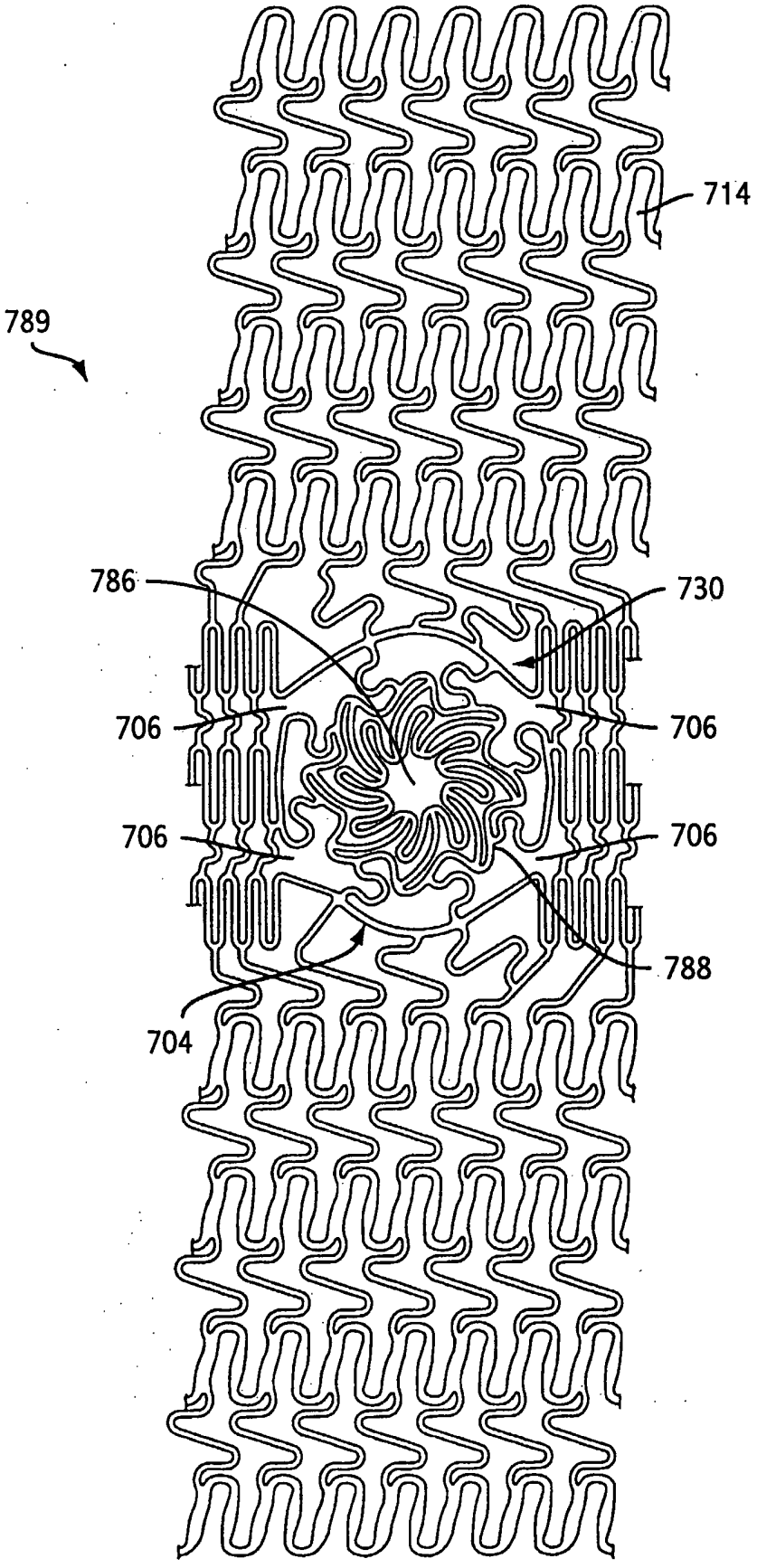


FIG. 17

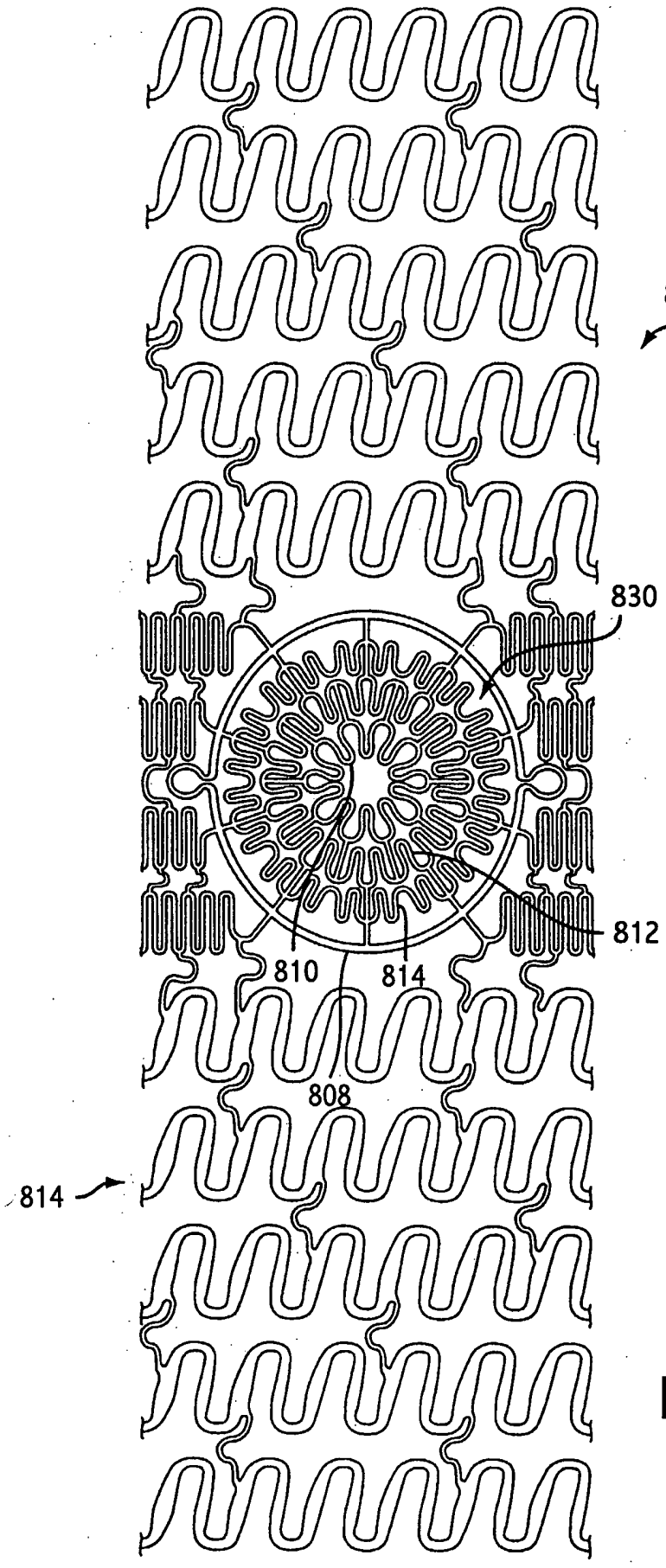


FIG. 18

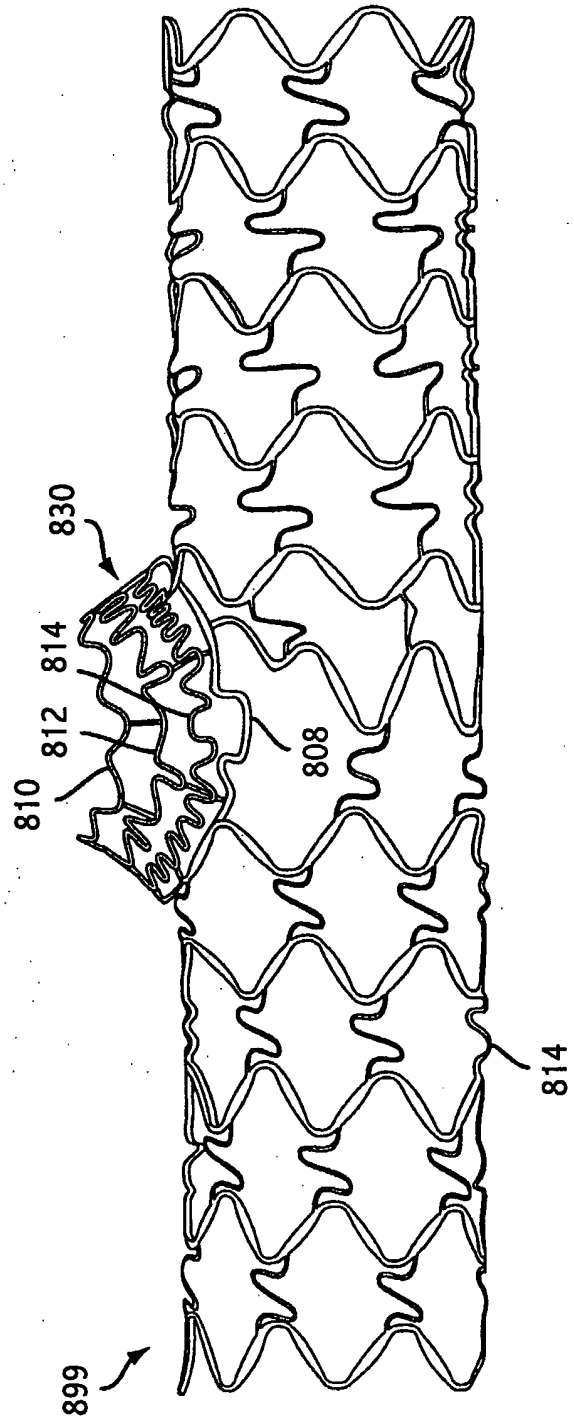


FIG. 19

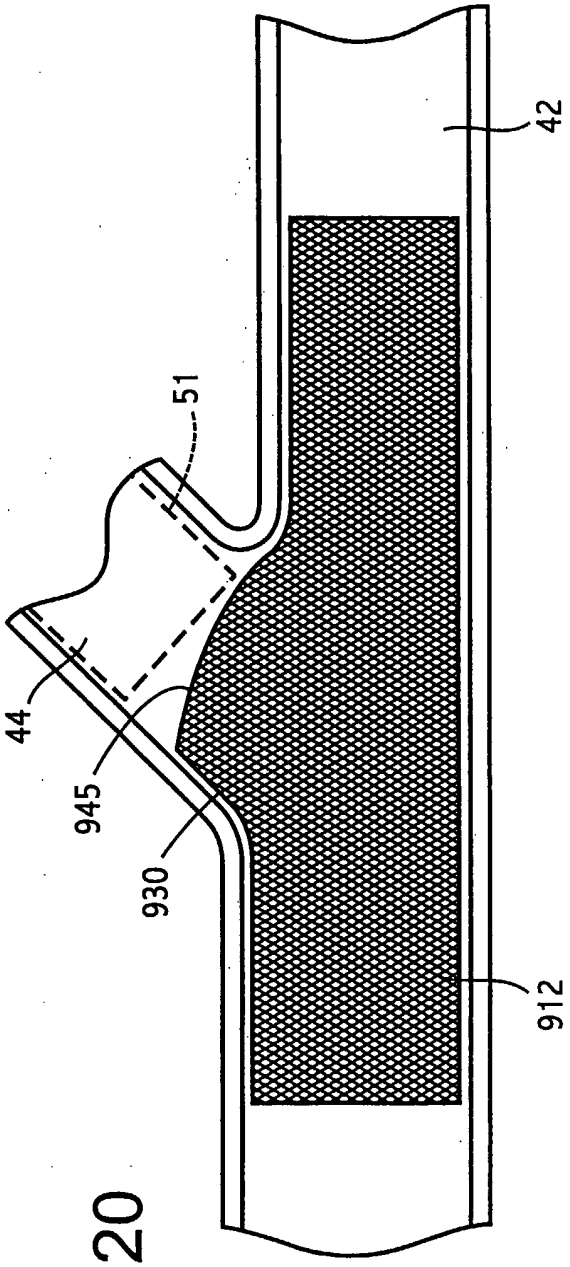


FIG. 20

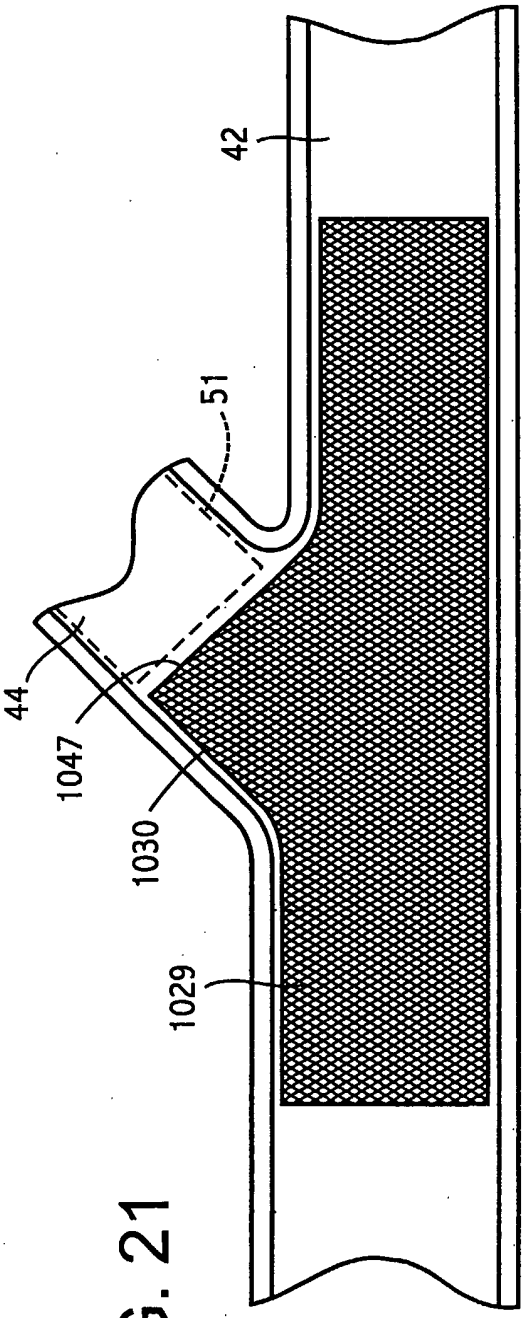


FIG. 21

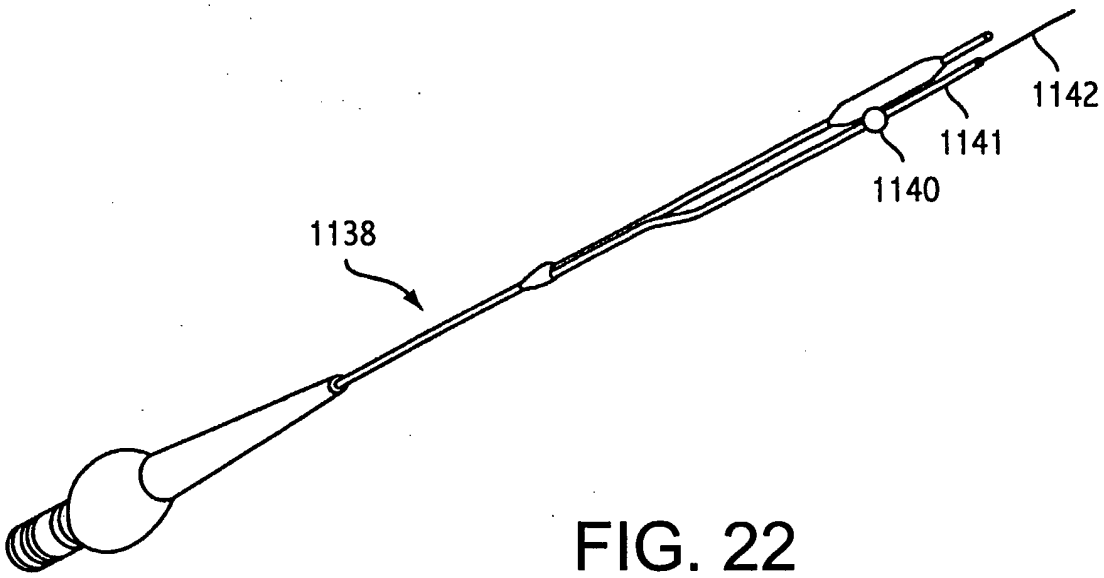


FIG. 22

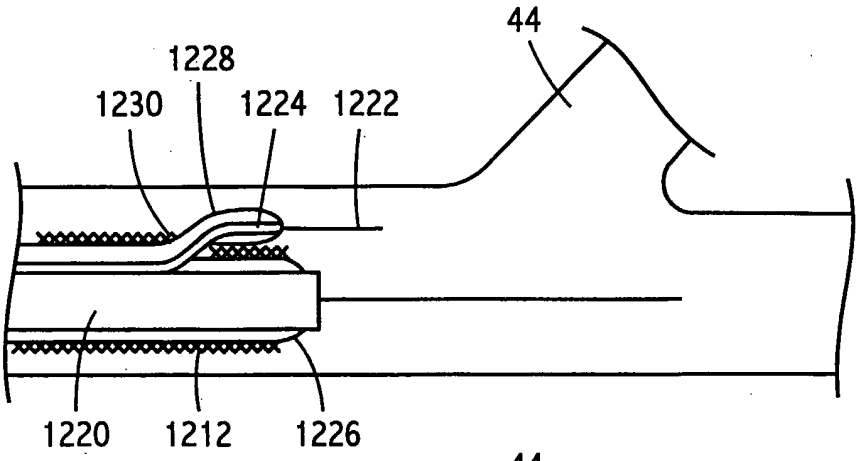


FIG. 23

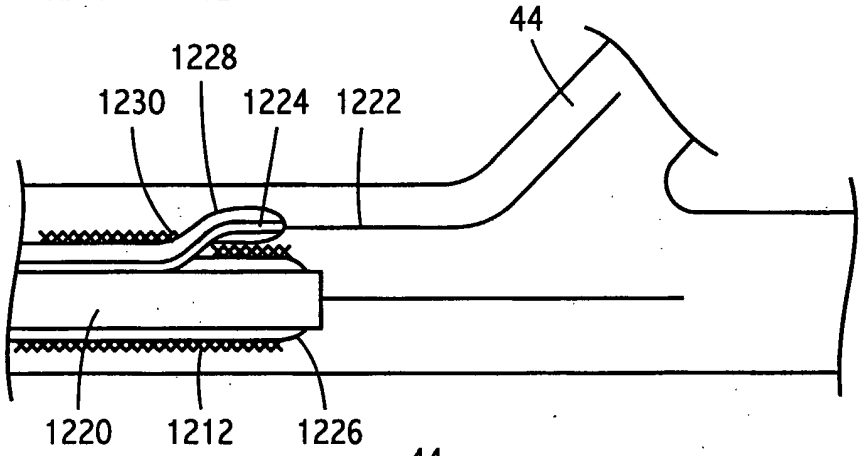


FIG. 24

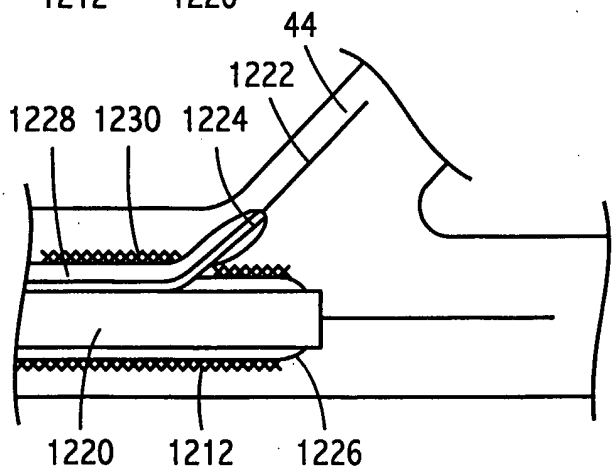


FIG. 25

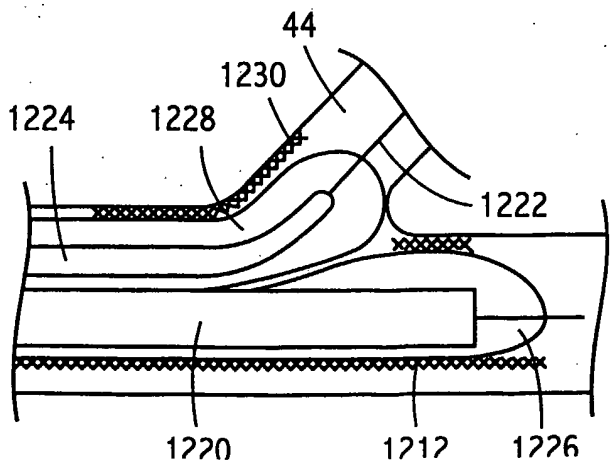


FIG. 26

INTERNATIONAL SEARCH REPORT

International Application No
PCT /US2005/ 025556

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/138737 A1 (DAVIDSON CHARLES J ET AL) 15 July 2004 (2004-07-15) paragraph '0071! paragraph '0073! paragraph '0076! paragraph '0057! claims 2-4 figures 11,14,15,25-28	1-8, 14-30

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier document but published on or after the international filing date

'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

'O' document referring to an oral disclosure, use, exhibition or other means

'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

'&' document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 2005	04/11/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 31-43

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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Continuation of Box II.2

Claims Nos.: 9-13

The subject matter defined by claim 1 and one of the dependent claims 9-13 discloses a system where, implicitly three expandable balloons are disclosed (a first balloon associated with the main catheter shaft, a second balloon associated with a side sheath and a third balloon defined by a inflatable portion of a second branch portion located at the distal end of the main catheter shaft). The reason is the following:
While subject matter of claim one defines the embodiment where the second balloon is attached to the side sheath, the subject matter of one of the claims 9-13, describes this second balloon as being an inflatable portion of the second branch portion of the main catheter shaft.

The defined subject matter is therefore obscure as it is not understood how the described system could perform with three inflatable portions.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31-43
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 9-13
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/025556

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004138737 A1	15-07-2004	NONE	